Mobile Health Approaches in the Assessment and Treatment of Overweight and Obesity

Inaugural-Dissertation

in der Fakultät Humanwissenschaften

der Otto-Friedrich-Universität Bamberg

vorgelegt von

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aus

Köln

Bamberg 2025

Diese Arbeit hat der Fakultät Humanwissenschaften der Otto-Friedrich-Universität Bamberg als Dissertation vorgelegen.

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Tag der mündlichen Prüfung: 29.04.2025

URN: urn:nbn:de:bvb:473-irb-1082357
DOI: https://doi.org/10.20378/irb-108235

Acknowledgments

'Which is more important,' asked Big Panda, 'the journey or the destination?'
'The company.' said Tiny Dragon.' *James Norbury, 2021*

Auf dem Weg zu dieser Arbeit hatte ich das große Glück, von vielen wunderbaren Menschen begleitet zu werden. Menschen, mit denen ich diskutieren, nachdenken, verzweifeln und vor allem lachen konnte. Menschen, die mich inspiriert, bereichert, unterstützt und herausgefordert haben und die maßgeblich dazu beigetragen haben, dass ich meine Promotionszeit als eine spannende und bereichernde Phase in Erinnerung behalten werde.

Mein besonderer Dank gilt Prof. Dr. Sabine Steins-Löber und Prof. Dr. Jörg Wolstein für die wissenschaftliche Betreuung meiner Promotion und die Begutachtung dieser Arbeit. Vielen Dank für das Vertrauen und die Flexibilität, die ihr mir jederzeit bei der Gestaltung meiner Forschung entgegengebracht habt. Ich bin sehr dankbar für eure Expertise und die entscheidenden Impulse, die ihr mir gegeben habt.

Vielen Dank an die Teams, die mir die Zusammenarbeit so leicht gemacht haben: I-GENDO, I-PREGNO, KlinPsych und PathoPsych. Danke an Theresia, Kerstin, Tobias, Frank, Dani, Niklas, Ansgar, alle Studienteilnehmer:innen und alle engagierten Hilfskräfte und Student:innen! Besonders bedanken möchte ich mich bei Dr. Stefanie Schroeder und Prof. Dr. Johanna Löchner, die ich in verschiedenen Phasen meiner Promotion kennenlernen durfte und die mir beide sehr wichtige Werte vorgelebt und vermittelt haben.

Ein großes Dankeschön geht an meine Fellow Doktorand:innen – Tanja, Carmen, Lena, Lea, Janis und Natalie. Ohne euch hätte ich das alles nicht geschafft. Danke für das gemeinsame Durchstehen von Höhen und Tiefen, eure aufmunternden Worte, die unzähligen Teams-Calls, Schreibsessions, R-Sessions, Feedbackschleifen und vor allem die vielen Momente der Unbeschwertheit und Verbundenheit.

Mein besonderer Dank gilt meiner Familie und meinen Freundinnen. Danke für eure Loyalität, treue Unterstützung und stetige Ermutigung. Danke an euch, Susi und Ben, für den entscheidenden Anstoß und dafür, dass ihr immer für mich da seid.

Danke an dich, Andi, dass du immer an meiner Seite bist und mich in genau den richtigen Momenten herausforderst. Deine Geduld, dein unerschütterliches Vertrauen in mich und deine Bereitschaft Aufgaben zu übernehmen haben mir den Rücken gestärkt und mich motiviert weiter zu machen. Danke vor allem dafür, dass du mir so viel Leichtigkeit schenkst und mich so oft zum Lachen bringst.

Summary

Overweight and obesity are associated with a wide range of physical and psychological consequences. The associated loss of quality of life and high levels of psychosocial burden can motivate individuals with overweight and obesity to engage in weight loss activities. Research shows that participating in a behavioral weight loss program successfully changes diet and physical activity behavior and leads to weight loss. However, the behavior change is often not sustained leading to unfavorable emotional experiences and weight gain. Furthermore, despite the increasing prevalence of overweight and obesity worldwide, there is a lack of adequate and sustainable treatment options. This gap in care can be addressed by providing novel digital assessment and intervention approaches that consider the complexity of overweight and obesity. Mobile health (mHealth) interventions delivered through smartphone apps are particularly well suited because they can improve health behaviors in everyday life, offer low-threshold access, and can be widely disseminated. However, even digital behavioral interventions have shown only short-term effectiveness. For the treatment of overweight and obesity, intervention approaches are needed that enable sustainable behavior change.

This dissertation aims to 1) provide an overview of the current evidence and effectiveness of (digital) behavioral weight loss interventions, and 2) introduce two promising approaches that could increase the long-term impact of intervention effects. First, the integration of underlying emotional and cognitive factors in assessment and intervention studies, and second, the consideration of sex/gender as an individualization approach in mHealth treatment. The body of this thesis consists of four original studies, each of which contributes to these two objectives.

Study 1 examined the bi-directional association between affective determinants (i.e., core affect) and daily physical activity within a 7-day ecological momentary assessment (EMA) study. Core affect is an understudied key facet for behavior change in individuals with overweight and obesity, and EMA studies examining this affect-physical activity association in the context of overweight and obesity are lacking. For this study, data from 157 adults (Body Mass Index, BMI: 32.99±3.87 kg/m^2) were included in a multilevel model analysis. Participants wore an accelerometer and completed EMA surveys for seven consecutive days. Results showed a significant bi-directional association between physical activity and energetic arousal and calmness, but not valence. This suggests that the affect-enhancing response to physical activity differs from the experience of individuals with a BMI below 25. When designing

mHealth interventions, consideration should be given to setting realistic expectations about the impact of daily physical activity and modifying these affective determinants.

Study 2 presented the development process, usability, and acceptability of the individualized gender-sensitive mHealth intervention I-GENDO. This self-guided multi-component intervention was designed to change cognitive and emotional aspects related to weight and weight-related behaviors by offering cognitive-behavioral treatment strategies that were offered in two gender-sensitive variants. Analysis of the usage patterns of 116 participants (BMI: 33.07 kg/m^2) who used the I-GENDO intervention for 12 weeks showed that the app was used for an average of 625 minutes by female participants and 347 minutes by male participants, and that overall usage time decreased during the intervention period. Significant sex/gender differences were found in engagement with the app, but not in ratings of acceptability, usability, and satisfaction. The gender-sensitive custom treatment options were successfully implemented, but further research is needed to understand the motivation of female and male users to choose a particular treatment variant.

Study 3 examined whether the use of the 12-week gender-sensitive mHealth intervention I-GENDO changes weight-related behaviors (i.e., eating behavior, physical activity) and weight (i.e., BMI) in women and men. We conducted a randomized controlled trial (RCT) that included 116 participants in the intervention group and 97 women and men in the control group (BMI: 33.58 kg/m^2). By addressing the underlying cognitive and emotional aspects of overweight and obesity through the I-GENDO intervention, improvements in eating behavior and small reductions in BMI were achieved. However, the effects were mixed in terms of sustainability and differed by sex/gender. The results confirm that cognitive-based health behaviors in particular can be modified by the self-guided mHealth intervention. However, the robustness of the effectiveness of the intervention remains limited, mainly because the chosen design of the study prevents concrete statements about the effectiveness of the novel gender-sensitive approach and individualization features.

In Study 4, guidelines for digital technology researchers and practitioners on how to develop, evaluate, and implement mHealth assessments and interventions in healthcare are proposed. The findings of the I-GENDO evaluation and intervention studies informed the development of these guidelines as well as current literature. The guidelines were developed using an adapted Delphi process among 25 authors with expertise in digital mental health, and cover topics such as intervention content development, user-centered design, participatory approaches, privacy, artificial intelligence, sensors and wearables, evaluation of effectiveness,

and transfer to clinical practice. The need for feasible interventions and long-term follow-up measurements is emphasized.

In summary, the findings of this dissertation highlight the importance of assessing cognitive and emotional processes, and health behaviors in everyday life, which can inform the timing and development of individualized mHealth interventions. The results of the presented studies provide important novel insights into how to implement cognitive and emotional mechanisms that influence health behavior in a gender-sensitive treatment approach for digital obesity treatment. At the same time, this work also highlights current limitations and discusses future directions for the development and evaluation of individualized psychological interventions, such as low user engagement and adherence.

Preamble

This dissertation includes four peer-reviewed articles, which have all been published in international journals in English language. All four original studies are embedded in this dissertation (Chapter 2 – Chapter 5) and can be read independently.

Study 1 | Chapter 2

Seiferth, C.*, Fiedler J.*, Färber, T., Pape, M., Schroeder, S., Herpertz, S., Steins-Loeber. S., Wolstein, J. (2024). Bi-directional associations of core affect and physical activity in adults with higher body weight: An ecological momentary assessment study. *Journal of Health Psychology*, *29*(10). 1115-1128. https://doi.org/10.1177/13591053241228202

Study 2 | Chapter 3

Pape, M., Färber, T., **Seiferth, C.,** Roth, T., Schroeder, S., Wolstein, J., Herpertz, S., Steins-Loeber, S. (2022). A Tailored Gender-Sensitive mHealth Weight Loss Intervention (I-GENDO): Development and Process Evaluation. *JMIR Formative Research*. *6*(10): e38480. URL: https://formative.jmir.org/2022/10/e38480. DOI: 10.2196/38480.

Study 3 | Chapter 4

Seiferth, C.*, Färber, T.*, Pape, M., Schoemann, N., Dieberger, A., Schroeder, S., Herpertz, S., Wolstein, J., Steins-Loeber, S. (2023). Differential effects of the individualized gender-sensitive mHealth intervention I-GENDO on eating styles in individuals with overweight and obesity–a randomized controlled trial. *BMC Digital Health*, *1*(1), 46. https://doi.org/10.1186/s44247-023-00041-0

Study 4 | Chapter 5

Seiferth C.*, Vogel L.*, Aas, B., Brandhorst, I., Carlbring, P., Conzelmann, A., Esfandiar, N., Finkbeiner., M., Hollmann, K., Lautenbacher, H., Meinzinger E., Newbold, A., Opitz, A., Renner, T.J., Sander, L.B., Santangelo, P.S., Schoedel, R., Schuller, B., Stachl, C., Systelios think tank, Terhorst, Y., Torous, J., Wac K., Werner-Seidler, A., Wolf, S., Löchner, J. (2023). How to e-mental health: a guideline for researchers and practitioners using digital technology in the context of mental health. *Nature Mental Health*, *1*(8), 542-554. https://doi.org/10.1038/s44220-023-00085-1

*Authors contributed equally to this work.

The author of this dissertation, Caroline Seiferth, was involved in the preparation and publication of all four manuscripts in collaboration with the co-authors mentioned above. The original studies 1, 2, and 3 are based on the data from a randomized controlled trial (RCT) of the I-GENDO project which was funded by the German Federal Ministry of Education and

Research (Grant: 01GL1719A/B). Caroline Seiferth was involved in the development of the overall study design of the RCT and was responsible for the development of the I-GENDO mHealth intervention, the recruitment of study participants, data collection, and data analysis at one of the two German study sites at all four assessments. For Study 1 (see Chapter 2) and Study 3 (see Chapter 4) within the I-GENDO project she developed the hypothesis, recruited participants, collected data, analyzed the data, and took the lead in writing the manuscripts under the supervision of Professor Dr. Sabine Steins-Loeber and Professor Dr. Jörg Wolstein. As a co-author, she was involved in the hypothesis generation, data analysis, and interpretation of the results of the original Study 2 (see Chapter 3). She also contributed to the drafting of the manuscript. Study 4, presented in Chapter 5, was prepared by Caroline Seiferth under the supervision of Professor Dr. Johanna Löchner in collaboration with several experts in the field of digital mental health. Caroline Seiferth was responsible for the conceptualization of the study and supervised the writing process and the implementation of the Delphi-adapted process, conducted the literature search, and took the lead in writing the introduction, discussion, and the ‘where to start’ and ‘intervention content development’ sections.

Table of Contents

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List of Abbreviations

ACT	Acceptance and Commitment Therapy
AI	Artificial Intelligence
BCT	Behavior Change Techniques
BMI	Body Mass Index
CBT	Cognitive Behavioral Therapy
DAG	Deutsche Adipositas-Gesellschaft/German Obesity Association
DBT	Dialectical Behavioral Therapy
DiHA	Digital Health Applications
eHealth	Electronic Health
EMA	Ecological Momentary Assessment
GPS	Global Positioning System
MBCT	Mindfulness Based Cognitive Behavioral Therapy
mHealth	Mobile Health
NCD-RisC	NCD Risk Factor Collaboration
I-GENDO	An Individualized Gender-Sensitive mHealth Intervention for Overweight and Obesity
JITAI	Just-in-time Adaptive Interventions
MOST	Multiphase Optimization Strategy
NEAT	Non-Exercise Activity Thermogenesis
PPI	Patient and Public Involvement
RCT	Randomized Controlled Trial
UCD	User Centered Design
WHO	World Health Organization

Abbreviations that were used in the original studies in Chapter 2 to 5 can be found in the abbreviation list of each manuscript.

Chapter 1 | Theoretical Background

1.1 Introduction

"Body mass is a biometric characteristic and refers to a person's physical mass, usually expressed in kilograms (kg)" ("Körpergewicht", 2024). Despite this straightforward definition, body mass is a subject of emotional debate in many social, political and, especially health contexts. At first glance, body mass is a very individual and intimate topic, influenced by many aspects, that does not lend itself to generalization and categorization. In the medical field, however, body mass is categorized and evaluated to identify ranges that are considered harmful to health and associated with somatic complaints and secondary diseases: underweight or overweight. Everything in between is considered "normal" or "ideal" weight. However, there are people in all weight ranges who are not satisfied with their weight or who experience social judgment because of their weight. This is where the psychological perspective comes in, and how people perceive and evaluate body weight and bodies in general, and what kind of feelings and behaviors are associated with them. These considerations illustrate that despite its simple definition, body mass is fraught with medical, psychological, and social complexities, and that a multimodal approach is needed to address body weight.

When it comes to addressing extreme overweight (i.e., obesity) – one of the world's most prevalent and persistent noncommunicable diseases - weight loss represents a primary goal. When thinking about how to lose weight, behavioral approaches are often the first ones to come to mind. In addition, bariatric procedures are used to achieve changes in body mass. Recently, there have also been breakthroughs in the use of pharmacotherapeutic weight loss methods. Regardless of the influence of these methods on body mass changes, it is important not to neglect the role and influence of the aforementioned psychological factors associated with weight, such as emotions (e.g., shame, frustration) and cognitions (i.e., self-control, self-efficacy). Comparable to the treatment of mental illnesses, such as major depression, pharmacological approaches alone are not sufficient to achieve lasting change. Psychological support is needed in the treatment and management of weight to appropriately accompany changes in body mass and to change the underlying factors that maintain and trigger certain types of behaviors.

Therefore, people who want to lose weight need comprehensive psychological counseling and therapy. In most European countries, the need for psychotherapeutic services is greater than the supply, which is why the number of accessible digital approaches has increased significantly in recent years. Mobile or web-based psychotherapy services have the potential to reach large numbers of people. In addition to the promising benefits, many different challenges remain,

including: What approaches can be used? What emotional and cognitive factors should be the focus of digital assessments and interventions for individuals with obesity? How can psychological services be tailored to be relevant and accepted by users? And how effective are these services over the long term?

This dissertation focuses on digital assessment and intervention approaches in the context of overweight and obesity that incorporate psychological aspects. To address the above questions, the theoretical background of psychological treatment of obesity and existing digital approaches are systematically summarized. Concrete research questions are derived and four original publications that examine the usability and effectiveness of digital assessment and intervention solutions are presented and discussed.

1.2 Overweight and Obesity

Overweight is described as a body weight above the threshold of reference values, which are based on population distributions (Komaroff, 2016). Obesity is defined "as a condition of abnormal or excessive fat accumulation in adipose tissue, to the extent that health may be impaired" (WHO, 2000, p.6). Both definitions suggest that there are reference values to which an individual's height and weight must be compared to be classified as having overweight or obesity. The most common way to do this is to create a weight-for-height index (Kuczmarski & Flegal, 2000). In 1997, the World Health Organization (WHO) proposed a weight classification that is based on cut-off points of the most widely used weight-for-height index, the body mass index (BMI; Eveleth, 1996; WHO, 1998, 2000). The BMI is a measure of an individual's body weight status calculated by dividing the individual's body weight in kilograms by the square of the individual's height in meters (WHO, 2000). The weight categories and corresponding BMI cut-off points suggested by the WHO are defined as: 'underweight' ($\leq$18.5 kg/m^2), 'normal weight' (18.5 kg/m^2 to 24.9 kg/m^2), 'overweight' ($\geq$25.0 kg/m^2), and 'obesity' ($\geq$30.0 kg/m^2). The category obesity is further subdivided by degree of severity: 'obesity class I' (30.0 kg/m^2 to 34.9 kg/m^2), 'obesity class II' (35.0 to 39.9 kg/m^2) and 'obesity class III' ($\geq$40.0 kg/m^2; WHO, 2000).

In this dissertation, I will use the terms 'overweight' and 'obesity' defined by the BMI cutoffs to describe individuals with higher body weight as they are commonly used in the academic and medical domain to date. Nevertheless, I acknowledge the important discourse about weight-related terminology that has been initiated in recent years by individuals with higher body weights, weight-related social justice organizations, researchers, and health

professionals (Meadows & Daníelsdóttir, 2016; Nutter et al., 2023; Puhl, 2019). It is important to recognize that weight-related terms such as ‘obesity’, ‘excess fat’ or ‘morbidly obese’ are not neutral descriptions of body mass, but tend to medicalize body weight and contribute to negative emotional responses (Brown & Flint, 2021) and weight stigma (Meadows & Daníelsdóttir, 2016; Nutter et al., 2023).

BMI is a popular measure of body weight at the population level because it is an indicator of percentage of fat mass, is economical to use in daily clinical practice, and allows for comparability across age groups and sex (Kuczmarski & Flegal, 2000). However, its use as a screening or diagnostic tool at the individual level has some notable limitations, primarily because it does not adequately address the complexity of the relationship between weight and health status (Flegal, 2023; Ruder, 2023). In addition, BMI provides limited information about fat distribution and individual body composition (e.g., muscle mass, subcutaneous fat) (Bosy-Westphal & Müller, 2021; Flegal, 2023). Supplementary measures such as body fat percentage, waist-to-hip ratio, and muscle strength should be considered to better assess health risks (Bischoff, 2018; Herpertz et al., 2022).

1.2.1 Prevalence, Etiology, and Consequences

In 2022, 2.5 billion adults worldwide were estimated to be overweight (i.e., BMI ≥ 25), including 890 million who were affected by obesity (i.e., BMI ≥ 30) (WHO, 2024). Trends in adult BMI in 200 countries from 1975 to 2016 were examined in studies by the NCD Risk Factor Collaboration (2016, 2017). Globally, the age-standardized prevalence of obesity increased from 3.2% in 1975 to 10.8% in 2014 for men and from 6.4% to 14.9% for women (NCD-RisC, 2016). In 2016, the age-standardized prevalence of obesity in the United States was 37.5% for men and 39.5% for women (NCD-RisC, 2017). Cross-sectional data from Germany showed that in 2020, 19.0% of women and men reported a BMI ≥ 30, i.e., obesity (Schienkiewitz et al., 2022). According to long-term projections of obesity rates in 18 European countries and the United States, the prevalence of obesity among adults aged 20 to 84 will reach 31% by 2037 (Janssen et al., 2020), indicating a continuation of the steady rise in global obesity trends (Blüher, 2019).

Etiologically, the development of excess body weight is due to a long-term positive energy balance (Hill, 2006). Simply put, overweight and obesity are caused by energy intake (i.e., the number of calories consumed) being greater than energy expenditure (i.e., the number of calories expended). However, from a biopsychosocial perspective, this chronic imbalance in energy homeostasis is the result of complex interindividual interactions among genetic,

epigenetic, metabolic, behavioral, psychological, neuroendocrine, sociocultural, and environmental factors (Goodarzi, 2018; Rubino, 2019; Russell & Russell, 2019; M. W. Schwartz et al., 2017). This approach reduces the simplicity of the energy balance principle by emphasizing that the development of obesity is multifactorial (Hall et al., 2022; Stroebe, 2022, 2023). The factors that directly influence energy intake and energy expenditure are dietary and physical activity behaviors (Marlatt & Ravussin, 2020). In turn, bio-psycho-social factors such as genetics, metabolic processes, or environmental factors influence food intake and physical activity levels (Stroebe, 2022). Based on this proposed multi-factorial etiology, it can be concluded that the prevention and treatment of obesity require multifactorial treatment strategies that address individual-level (i.e., biological, physiological, and psychological processes) and population-level (i.e., environment) factors that influence energy balance.

The WHO and the World Obesity Federation describe obesity as a chronic and relapsing disease that requires systematic and comprehensive solutions (Bray et al., 2017; WHO, 2024). This position is motivated by the increased risk for several physical (e.g., cardiovascular disease), psychological (e.g., depression), and social (e.g., weight stigma) consequences that are associated with higher body weight and that affect quality of life, well-being, and mortality (GBD 2015 Obesity Collaborators, 2017; Taylor et al., 2013). The most common physical diseases associated with obesity are non-communicable diseases, such as cardiovascular diseases, asthma, impairments of the musculoskeletal system, Type 2 diabetes, and various forms of cancer (Guh et al., 2009). In addition to these physical comorbidities, overweight and obesity are also associated with a range of psychosocial burdens.

Cross-sectional and longitudinal studies suggest that individuals with obesity have a higher prevalence of anxiety disorders (Gariepy et al., 2010), binge-eating-disorder (de Zwaan, 2001), and major depression (de Wit et al., 2010; Luppino et al., 2010; Pereira-Miranda et al., 2017) compared to individuals with overweight or normal weight. The relationship between obesity and depression is considered to be U-shaped, with higher depression scores in both individuals with underweight and obesity (Carey et al., 2014). A meta-analysis by Luppino and colleagues (2010) found a bi-directional association: individuals with obesity have a 55% increased risk of developing depression, while individuals with depression have a 58% increased risk of developing obesity (Luppino et al., 2010). While the evidence for this bi-directional relationship is growing, the underlying mechanisms remain debated (Milano et al., 2020). Behaviorally, depression and obesity may be mutually reinforcing, as higher body weight can reduce self-esteem and lead to social isolation, particularly in environments where

weight stigma is prevalent. This can lead to reduced physical activity and unhealthy coping behaviors (Luppino et al., 2010; Milano et al., 2020). Overall, the reciprocal and multifactorial nature of obesity and its physiological and psychological comorbidities points to the need for therapeutic approaches that address these different levels.

1.2.2 Treatment

National and international guidelines echo this view by stating that a comprehensive lifestyle intervention should be the foundation of any obesity treatment (Deutsche Adipositas Gesellschaft (DAG) e.V., 2024; Durrer Schutz et al., 2019). Lifestyle intervention or behavioral intervention is a conservative approach to obesity treatment that combines exercise, diet, and behavioral therapy. According to the guidelines, adjunctive treatments such as pharmacotherapy or bariatric surgery (e.g., gastric bypass, sleeve gastrectomy) are indicated only in the cases of a higher BMI, greater health risks, and after a failure to lose weight with lifestyle interventions (DAG, 2024). Considering the significant developments and weight loss successes achieved in recent years with the selective glucagon-like peptide-1 receptor agonist semaglutide in the area of anti-obesity medications (Bergmann et al., 2023; Chao et al., 2023), the indications and recommendations for pharmacotherapy were substantially adjusted. Even if the use of pharmacotherapy is to be increased, it is essential to establish an adequate overall treatment approach that includes the provision of behavioral and psychological support (Fallows et al., 2023).

The majority of lifestyle interventions focus on providing specific dietary and physical activity recommendations and using behavioral strategies to achieve a negative energy balance (Olateju et al., 2021). Behavioral strategies increase an individual's understanding of specific triggers that influence problematic weight-related behaviors, identify and modify weight-related emotions and cognitions, improve stress management, practice flexible self-control behaviors, implement social support structures, and prevent relapse (DAG, 2024; Olateju et al., 2021). To facilitate these behavioral changes, behavior change techniques (BCTs) are used. BCTs are active intervention components that are "observable, replicable and irreducible component[s] of an intervention designed to alter or redirect causal processes that regulate behavior" (Michie et al., 2013, p. 82). Examples of BCTs include self-monitoring of behavior, goal setting, social support, alternative behaviors, problem solving, cognitive restructuring, or restructuring of the physical environment (Michie et al., 2013).

Although there is considerable heterogeneity in intervention design (e.g., length, number of sessions, mix of content), there is ample evidence that the use of such comprehensive

behavioral lifestyle interventions leads to meaningful, albeit modest, weight loss in individuals with overweight and obesity (e.g., Lv et al., 2017; Madigan et al., 2022; Wadden et al., 2020). For example, Wadden and colleagues (2020) showed that high-intensity lifestyle interventions can result in mean weight loss of up to 8% at six months and up to 12% mean weight loss at one year. For classification purposes, successful weight loss is defined as an intentional weight loss of at least 5% (BMI 25 – 35 kg/m^2) or 10% (BMI ≥ 35 kg/m^2) of baseline weight over six to twelve months that is maintained for at least one year (DAG, 2024; Wing & Hill, 2001). The meta-analyses presented above suggest that lifestyle interventions can lead to successful weight loss in the majority of participants. However, the results do not indicate the extent to which these interventions are successful in maintaining weight loss over the long term.

Following successful weight loss, weight maintenance is the more critical phase of weight management. The "challenge of keeping it off" is described in the systematic review by Nordmo and colleagues (2020). They searched for high-quality randomized controlled trials (RCTs) of lifestyle interventions that achieved at least 5% of the initial weight loss, offered no further intervention in the follow-up period, and had at least three years of follow-up. The authors identified only eight RCTs that met the eligibility criteria. In seven of these eight interventions, the meaningful weight loss assessed at post-treatment diminished over time. On average, participants regained weight and returned to their pre-treatment baseline weight over up to five years of follow-up (Nordmo et al., 2020). This finding confirms observational data from Germany, indicating that only 12% of individuals achieve five-year weight loss maintenance (de Zwaan et al., 2008). These results have several implications. On the one hand, the difficulty of long-term weight loss should reinforce the importance of preventive approaches in general, and on the other hand, it is important to identify the factors that facilitate long-term weight maintenance. In recent years, obesity research has focused on identifying antecedents for sustained behavior change and long-term maintenance of weight loss. Approaches that have emerged include integrating the emotional and cognitive processes that underlie behavior and targeting treatment to these processes based on individual needs and characteristics.

1.3 Factors Influencing the Treatment of Overweight and Obesity

Previous research has identified emotional and cognitive determinants that positively (e.g., motivation, autonomy, self-efficacy for exercise and weight management) or negatively (e.g., high internal disinhibition, worsening body image, lower ability to tolerate uncomfortable internal reactions to food stimuli) predict successful weight management (Phelan et al. 2023;

Santos et al., 2015; Teixeira et al., 2015; Teixeira et al., 2005; Varkevisser et al., 2019). Based on this literature, it is believed that sustainable long-term changes in eating behavior and physical activity can occur when the underlying emotional and cognitive processes of the key health behaviors, eating behavior and physical activity behavior, are identified and addressed.

1.3.1 Emotional Processes

The link between emotional processes and weight-related behaviors in individuals with overweight and obesity has been observed primarily in the context of emotional eating. This specific eating behavior is triggered by emotional cues (e.g., sadness, boredom, anxiety, or aggression/anger) and describes an individual's tendency to increase food intake in response to an emotional cue as opposed to a physiological need (van Strien et al., 1986). According to psychosomatic theory, the level of physical arousal which is present when experiencing an emotion is interpreted as hunger and hence leads to food intake (Kaplan & Kaplan, 1975). Emotional eating is more prevalent in individuals with obesity than in individuals with overweight or normal weight, contributing to weight gain, and hindering weight loss (Frayn & Knäuper, 2018; Markey et al., 2023; Vasileiou & Abbott, 2023). That is because these emotional eating patterns lead to chronically unfavorable eating behaviors since eating as a means to regulate emotions may bring short-term relief, but then leads to further negative emotions such as shame, frustration, and self-criticism. To break out of this vicious cycle, it is not sufficient to follow certain dietary recommendations; instead, the psychological drivers of these behaviors must be understood and modified, and alternative strategies for the regulation of emotions must be developed. Research on emotional difficulties in obesity is limited, but evidence suggests that there is no generalized deficit in processing emotions (Andrei et al., 2018; Fernandes et al., 2018). Compared to normal-weight individuals, abnormalities in the emotion avoidance processes were associated with obesity, suggesting difficulties in identifying emotions, limited use of adaptive emotion regulation strategies and a higher tendency to use emotion suppression such as emotional eating (Andrei et al., 2018; Fernandes et al., 2018).

The central role of affective processing on physical activity behavior has been extensively studied in the general population (e.g., Liao et al., 2015; Reed & Ones, 2006). Literature suggests a bi-directional relationship between physical and core affect, indicating that physical activity leads to feeling better, and feeling better leads to higher levels of physical activity (Forster et al., 2021; Reed & Ones, 2006). Therefore, dimensions of core affect (i.e., valence, energetic arousal, calmness) predict whether an individual will be active or not, and if physical activity behaviors will be repeated. Studies show that individuals with obesity are less likely to

achieve adequate levels of physical activity than their normal-weight counterparts (Cassidy et al., 2017; Ladwig et al., 2021). Based on these findings, it can be assumed that dimensions of core affect, in addition to physical limitations, may influence the uptake of physical activity. There is considerable evidence to support the notion of activity-induced displeasure among individuals with overweight and obesity (Ekkekakis & Lind, 2006; Ekkekakis et al., 2016; Ekkekakis & Zenko, 2016; Hamer et al., 2021; Thedinga et al., 2021). However, there is a lack of studies outside of laboratory contexts (Berger et al., 2023; Ekkekakis & Lind, 2006; Ekkekakis et al., 2010; Unick et al., 2012) and a lack of knowledge about the underlying mechanisms of affective processes associated with the experience of physical activity in obesity (Ekkekakis et al., 2016). One possible explanation could be that the repeated experience of weight stigma could lead to negative emotional responses (e.g., fear of embarrassment) and, consequently, avoidance (Ekkekakis et al., 2016; Hamer et al., 2021; Thedinga et al., 2021). Weight stigma is described as when a person with a higher body weight faces face negative judgments and assumptions about their appearance (Wu & Berry, 2018) which is prevalent in a variety of contexts, including the workplace, healthcare settings, and everyday interactions with family, friends, and strangers (Giel et al., 2010; L. Ryan et al., 2023; Spahlholz et al., 2016). These experiences may represent a risk factor for the uptake of emotional eating and the avoidance of physical activity (Bidstrup et al., 2024; Emmer et al., 2020; Puhl et al., 2020; Schvey et al., 2011; Wu & Berry, 2018).

1.3.2 Cognitive Processes

These examples demonstrate that emotional processes are linked to health outcomes and key health behaviors that are associated with weight management. In addition to emotional processes, there are cognitive mechanisms that influence eating and physical activity behavior (e.g., Gunstad et al., 2020; Jansen et al., 2015). Systematic reviews and meta-analyses have analyzed individuals who have successfully maintained weight loss and identified several cognitive processes that are associated with weight regain and hinder successful weight loss maintenance (Elfhag & Rössner, 2005; Metzgar et al., 2015; Ohsiek & Williams, 2011), such as unrealistic weight loss expectations, a dichotomous thinking style (cognitive bias; "all or nothing"), and an uncontrolled eating behavior (Ohsiek & Williams, 2011). The specific cognitive functions that influence eating behavior are the executive functions, which represent a set of skills used to manage behavior and, in particular, enable goal-directed decision-making by balancing desired (e.g., controlled eating) and undesired behaviors (e.g., overeating). Executive functions include the ability to resist impulses and temptations and stop behavior

(i.e., inhibition), and the ability to remember to complete a task (i.e., working memory; Jansen et al., 2015). Increased deficits in these executive functions are associated with obesity (Yang et al., 2018), higher levels of impulsivity and overeating (Gunstad et al., 2020). From these findings, it can be concluded that higher executive function skills, i.e., high self-control, are necessary to engage in restrained eating and adhere to physical activity behaviors (Fan & Jin, 2014). Restrained eating, i.e., restricting food intake because of weight goals (van Strien et al., 1986), enhances successful weight loss and weight loss maintenance (Teixeira et al., 2010).

In summary, the evidence presented suggests that the effectiveness of lifestyle interventions can be increased by developing and implementing new comprehensive psychological treatments that focus not only on behavioral techniques but also on cognitive and emotional aspects. This could be achieved by incorporating Cognitive Behavioral Therapy (CBT) and emotion-focused treatment components (Becker et al., 2015; Z. Cooper et al., 2010; Z. Cooper & Fairburn, 2001; Munsch & Hilbert, 2015; Preuss et al., 2018). For example, Becker and colleagues (2015) proposed a CBT intervention which combines cognitive and behavioral techniques designed to systematically identify and modify unfavorable thought and behavioral patterns that maintain overweight. Additionally, it focuses on practicing behaviors and cognitive responses necessary for effective weight control and improved quality of life. In particular, it may be important to address each individual's potential underlying deficits, such as a lack of emotion regulation strategies or increased impulsivity. It is hypothesized that this may be the link that increases long-term effectiveness and the likelihood that an individual will maintain adherence to weight control techniques. In addition to emotional and cognitive processes, sex/gender differences observed in obesity prevalence, consequences, and treatment needs represent a promising starting point for individualizing psychological interventions.

1.3.3 Sex/Gender

Gender is being recognized as a relevant social determinant in the health research community (Miani et al., 2021; Tannenbaum et al., 2019). In this dissertation, I will follow the definition implemented in Springer and colleagues (2012) guidelines for researching sex/gender in human health. They define *sex* as the classification of human beings, according to their reproductive organs and functions, as determined by biological factors such as chromosomal, hormonal, and biomechanical (Springer et al., 2012). *Gender*, on the other hand, is defined as a person's self-presentation or identity, which is socially determined and based on how a person is treated and perceived by social institutions. Gender is rooted in one's biology and is shaped by one's environment and experiences (Springer et al., 2012). However, the distinction between

sex and gender is often ambiguous and the categories are intertwined, especially because gender normative and social exposures begin early in life, making it difficult to separate the biological from the sociocultural. Therefore, Springer and colleagues (2012) recommend using the term *sex/gender* to acknowledge the complexity of simultaneous biological and social influences and using the term *gender* when directly referring to sociocultural factors or norms that influence a person's experience. When referring to sex/gender differences in the context of overweight and obesity, it is important to note that previous studies have typically used a dichotomous categorization that refers to the gender binary system (woman-man, female-male; Hyde et al., 2019). The identities and experiences of transgender, gender diverse, nonbinary, and intersex individuals are missing from obesity research (B. Urban et al., 2024).

Women and men are likely to develop, experience and cope with obesity differently due to genetic, biological, environmental and socio-cultural influences related to gender norms, gender identities, and gender specific behavior. For example, at the biological level, it has been shown that adipose tissue function and deposition are influenced by sex hormones (i.e., estrogen) and therefore differ by sex/gender, with women having higher total body fat overall compared to men and men tending to have more visceral fat, which is associated with increased cardiovascular risk (Palmer & Clegg, 2015). Recent data from Germany indicate that more men (60.5%) than women (46.6%) have a BMI greater than 25 kg/m^2 (i.e., overweight). For obesity, however, the prevalence rates are similar at 19.1% (women) and 19.0% (men), suggesting that more men (41.3%) than women (27.6%) have a BMI between 25 and 30 (Schienkiewitz et al., 2022). There is evidence from the USA, for example, that the severity of obesity differs between men and women, with women (11.5%) having a higher prevalence of severe obesity (i.e., BMI > 40 kg/m^2) than men (6.5%; Hales et al., 2020).

Sex/gender differences do not only exist in prevalence, but also in various psychological mechanisms related to eating and physical activity behavior (e.g., stress, weight stigma, body dissatisfaction, emotional eating, depression, and motivation; A. J. Cooper et al., 2021). Studies show that women with obesity experience more weight-related stigma than men in the workplace (Giel et al., 2010) and in healthcare settings (Giel et al., 2012). A strong association between depression and obesity in women, but not in men, has been found in cross-sectional studies (Carey et al., 2014; de Wit et al., 2010; Heo et al., 2006), but not longitudinal studies (Luppino et al., 2010). In terms of body perceptions and body image, research suggests that weight-related attitudes to the body differ by sex/gender. Women with overweight are more likely to be dissatisfied with their bodies than men with overweight (M. B. Schwartz &

Brownell, 2004). This difference may be explained by the fact that men with a higher BMI (i.e., 25 - 35 kg/m^2), tend to have a less accurate perception of their weight and in turn a less problematic perception of their body (M. B. Schwartz & Brownell, 2004; Tsai et al., 2016).

These sex/gender differences in biological, social, and psychological mechanisms also affect health behaviors. For example, Sattler and colleagues (2018) suggest that experiencing weight stigma is a significant barrier to engaging in physical activity for women, as they found that higher weight stigma led to lower motivation to exercise, and lower levels of physical activity in women but not in men. With regard to sex/gender differences in eating behavior, there are neurobiological theories that obesity in female children is associated with greater reactivity to more energy-dense food cues (Keller et al., 2019). The state of research on sex/gender differences in emotional eating is mixed, with some studies suggesting that women report higher levels of emotional eating and stress-related eating (Ayyıldız et al., 2023; Christensen & Brooks, 2006; Cotter & Kelly, 2018; J. K. Larsen et al., 2006) and other studies finding no association between sex/gender and emotional eating (Mantau et al., 2018). Considering the level of emotional competence, Larsen and colleagues (2006) found that men with obesity who have difficulty identifying emotions and distinguishing between feelings and bodily sensations report higher levels of emotional eating.

Because gender is shaped by social contexts, available resources, and social roles it influences the development of health behaviors (Mollborn et al., 2020) and the selection of preferred weight management strategies. Sex distributions in different contexts show that the average male participation rate is 27% in RCTs testing weight loss interventions and 11% in commercial weight loss services (Pagoto et al., 2012; Robertson et al., 2014; Tsai et al., 2016). One reason for this underrepresentation of men in behavioral weight loss interventions may be the aforementioned differences in body weight dissatisfaction (A. J. Cooper et al., 2021). Research on low male enrollment has shown that men are motivated to start weight loss programs because of the health risks associated with obesity and the desire to improve their health, but they do not feel addressed by existing weight loss programs, which are often tailored to the needs of women and are predominantly attended by female participants (Elliott et al., 2020; Morgan et al., 2011; Wolfe & Smith, 2002).

Intervention research has focused on identifying sex/gender-specific intervention characteristics and treatment strategies in lifestyle interventions (Ashton et al., 2017; e.g., Robertson et al., 2016). For example, men with obesity tend to prefer treatments that increase their sense of autonomy and personal control (Robertson et al., 2016; Tsai et al., 2016), focus

on improving health and fitness, and create an all-male environment with peer support, team spirit, and competitive elements (Ashton et al., 2017; Morgan et al., 2011; Nguyen et al., 2024; Rosenfeld, 2017). These findings have been incorporated in male-specific programs such as the "Football Fans in Training" intervention that takes place in the football stadium of the male participants' favorite football clubs (e.g., Gray et al., 2018; Hunt et al., 2014). Research with female participants shows that they are motivated to engage in behavior change by emotional support, a sense of well-being, positive body image, and the enjoyment of being in a group (Ferrand et al., 2008; Rosenfeld, 2017).

The evidence on sex/gender differences in weight loss remains heterogeneous, with men tending to benefit more from weight loss programs. In their systematic review, Chopra and colleagues (2021) found that in four of 13 studies, being male was significantly associated with greater weight loss, while the remaining nine studies found no difference by sex/gender. These findings support the notion from previous systematic reviews that men lose relatively more weight than women (Stroebele-Benschop et al., 2013; Williams et al., 2015). Better treatment outcomes for men are thought to be related to higher average adherence to weight loss interventions (Burgess et al., 2017; Robertson et al., 2016). This suggests that when men do choose to participate in a program, they are more likely to complete it. To better understand this relationship, it would be important to report baseline data and weight outcomes disaggregated by sex/gender. This has rarely been done, making it difficult to directly compare intervention effects.

A recent meta-analysis by Sharkey and colleagues (2020) examined the effectiveness of 30 interventions targeted to sex (i.e., interventions designed for and attended either only by men or women) and 77 interventions not targeted to sex (i.e., interventions designed without regard to sex/gender differences and attended by both women and men) in adults aged 17 to 35 years. They found no statistical difference in overall weight loss between the targeted and non-targeted interventions. This finding suggests that there is a need not to target interventions based on biological sex and not to segregate women and men in interventions, but to provide gender-sensitive interventions that take into account sex/gender differences. However, the authors argue that further research on this topic is warranted and discuss the need for more targeted interventions to be able to make a meaningful comparison. They also highlight the lack of features that allow users to tailor the program specifics (i.e., considering personal characteristics, interests, preferences, and needs; Sharkey et al., 2020).

In summary, men and women tend to experience different consequences of obesity and show differences in the way they perceive and cope their higher body weight. This information should be used to inform the design of gender-sensitive intervention programs and to develop interventions that target these sex/gender-specific needs and life realities. However, evidence on the gender-specific design and effectiveness of weight loss interventions is lacking. Rather than developing interventions that follow the gender binary system and target either only men or only women, the development of gender-sensitive interventions that systematically take into account the different life situations and sociocultural contexts of males and females and allow users to tailor relevant content, could be promising. Such individualized treatment approaches require a high degree of customization and flexibility that digital approaches such as mobile health can provide.

1.4 mHealth in the Assessment and Treatment of Overweight and Obesity

The rise of digitalization and global challenges to mental well-being, such as the COVID19 pandemic (Blendermann et al., 2024), have acted as catalysts in recent years, promoting the spread of digital approaches, methods, and behavioral and psychological prevention and treatment interventions (Andersson et al., 2019; Torous et al., 2021). The field of digitally delivered interventions is heterogeneous and lacks consistent and common terminology (e.g., digital health, E-mental health, telepsychiatry, internet-delivered treatment, online intervention) and understanding, as digital health solutions vary, for example, in terms of the technology platform used (e.g., app-based, web-based) and the level of human or technical involvement (e.g., self-guided vs. guided; Smoktunowicz et al., 2020). Digital health can be understood as an umbrella term covering a wide range of information and communication technologies used to improve health, such as mobile health (mHealth). mHealth is defined as the use of mobile communication technologies such as mobile phones, tablets or medical sensors and functionalities such as applications (apps), Bluetooth or Global Positioning System (GPS; Cameron et al., 2017). It is the use of mobile communication technology to improve health by providing self-monitoring, diagnosis, educational content, health behavior change, and therapeutic interventions (Cameron et al., 2017). This widespread adoption brings several benefits to national healthcare systems, as mHealth offers low-threshold access and geographic independence (Meisenzahl & Sprick, 2023). Because of this accessibility and flexibility, individuals who would normally be unwilling or unable to participate in traditional care due to time constraints, geographic barriers, or concerns about stigma are more likely to be reached

by mHealth (Ebert et al., 2016). From an economic perspective, the increased scalability of the approaches could reduce healthcare costs (Gentili et al., 2022). In addition, mHealth solutions (e.g., wearable devices) allow researchers and practitioners to assess and modify an individual's behavior, cognitions, and emotions in their real- world contexts (Bradway et al., 2017). This mitigates the shortcomings of traditional assessment measures (e.g., questionnaires, laboratory behavioral tasks), which are based on retrospective and subjective assumptions. One of the most promising features of mHealth is the individualization and tailoring to socio-demographic, cultural and disease-specific aspects (e.g., Baumann et al., 2022; Davis et al., 2020).

mHealth approaches can be delivered in a variety of ways. Typically, delivery is categorized into self-guided/unguided (i.e., the individual uses an app without any human guidance), guided (i.e., the individual uses an app and receives asynchronous human support and feedback), or blended care formats (i.e., integration of face-to-face and unguided features; Meisenzahl & Sprick, 2023). Although many mHealth interventions have not been comprehensively evaluated (M. E. Larsen et al., 2019), meta-analyses suggest that guided mHealth approaches are more effective than self-guided approaches in delivering psychotherapy and behavioral interventions, but that self-guided approaches provide consistently better clinical outcomes than no treatment at all (Firth et al., 2017; Lindhiem et al., 2015; J. H. Wright et al., 2019).

This suggests that self-guided mHealth approaches can improve the current status quo, especially in domains where the existing healthcare systems are fragmented. One such area is the psychological and psychotherapeutic treatment of obesity (Frood et al., 2013). Non-digital psychological treatment is not commonly used as a standard of care outside of clinics (J. G. Thomas et al., 2019), creating a barrier and reducing access to the proposed holistic and multifactorial treatment. A report of a German health insurance company highlights the significant underuse and undertreatment of obesity in Germany (Nolting et al., 2016). They present data from 2015, in which the costs of multimodal treatment were covered for only 0.025% (i.e., 1 out of 4000) of insured persons between 20 and 70 years of age with diagnosed obesity. This percentage is grossly out of proportion to the actual prevalence of obesity. There are several reasons for this underuse, including a lack of knowledge among healthcare providers about evidence-based treatment options, and a lack of reimbursement for the therapeutic interventions needed to treat obesity. In turn, behavioral lifestyle interventions cannot be adequately utilized as there is currently no nationwide multimodal weight loss program offered in Germany (Blüher, 2021; Nolting et al., 2016). Therefore, there is a need for scalable treatment options that reduce the cost of treatment delivery and increase the reach of

interventions (Hinchliffe et al., 2022; Irvin et al., 2023). mHealth solutions for obesity treatment can fill this gap in service delivery by offering a new approach "that recognises the complexity of obesity and provides patient-centered, multidisciplinary care which more closely meets the needs of each individual with obesity" (Hinchliffe et al., 2022; p. 4398).

There are already mHealth solutions that cover the entire care pathway from prevention to treatment to rehabilitation in obesity care. When focusing on health behaviors and related emotional and cognitive processes, two approaches are relevant: assessment and intervention. Assessment allows for identification of associations between behavior, cognition, and emotions in everyday life and provides valuable insights into the underlying mechanisms of behavior. Interventions, on the other hand, provide psychoeducational and treatment strategies that, for example, enable the adaptation of favorable behavioral patterns or strengthen emotional and cognitive processes.

1.4.1 Assessment of Behavioral, Emotional, and Cognitive Factors

One method that has been increasingly used in recent years to assess psycho-behavioral variables and their intercorrelations in everyday life is ecological momentary assessment (EMA). Often used synonyms are ambulatory assessment, experience sampling method or real-time data collection (Myin-Germeys & Kuppens, 2021; Trull & Ebner-Priemer, 2013). EMA combines repeated assessments of subjective experience (e.g., emotional eating episodes) assessed through smartphone surveys with device-based measured passive data (e.g., heart rate, physical activity levels). The latter provides continuous real-time data on behavior that is ecologically valid and is assessed with accelerometers or wearable device sensors (Myin-Germeys & Kuppens, 2021). An important methodological advantage from using EMA is that it allows one to distinguish between intra-individual (i.e., within-person) and inter-individual (i.e., between-person) differences. Specifically, this means that the association between a behavior and an emotion can be analyzed relative to the average levels of a person (Trull & Ebner-Priemer, 2013). Compared to between-person designs, which are commonly used to detect differences between groups, this provides insight into the mechanisms of an individual and allows for the development of individualized interventions.

The implementation of EMA has brought several benefits to research in the field of overweight and obesity, such as the assessment of multiple dynamic processes in real time outside of laboratory settings (Engel et al., 2016; Trull & Ebner-Priemer, 2013). The aim is to inform clinical practice, the therapeutic process, and the diagnosis and monitoring of symptoms. Specific applications of EMA in obesity research include the identification of mechanisms that

contribute to the etiology and maintenance of obesity in general. More specifically, this includes the assessment of predictors and consequences of physical activity (e.g., mood), the exploration of eating patterns in different situational contexts, and the antecedents and consequences of loss of control over eating (Engel et al., 2016; Reichert et al., 2020). Bidstrup and colleagues (2024) emphasize the need for EMA studies to increase understanding of the nature of weight stigma and health correlates, such as higher disordered eating and lower positive mood. Further investigation of such associations is important to inform future interventions for designing multicomponent health behavior programs that target the underlying mechanisms.

1.4.2 mHealth Interventions in the Treatment of Overweight and Obesity

Findings from assessment studies inform the development of interventions that focus on modifying specific health behaviors (i.e., diet and physical activity) and changing underlying psychological aspects in individuals with overweight and obesity. According to the recommendations by guidelines (DAG, 2024; Durrer Schutz et al., 2019; Semlitsch et al., 2019), the combination of behavior modification strategies, physical activity, and nutrition therapy in multi-component mHealth interventions should be beneficial for improving health behaviors and reducing body weight in individuals with overweight and obesity. The technological capabilities of mHealth solutions allow for the design of multimodal interventions that provide information not only via text, but also via video or audio format, and increase user engagement with quizzes, self-assessments and gamification features.

Several systematic reviews and meta-analyses have demonstrated the effectiveness of mHealth behavioral interventions with the primary aim of changing diet, physical activity, or treating overweight and obesity (Islam et al., 2020; Qin et al., 2022; e.g., Schippers et al., 2017; Villinger et al., 2019). A random-effects meta-analysis of 41 trials that tested the effectiveness of nutrition apps that included BCTs (e.g., goals/planning, feedback/monitoring, shaping knowledge, social support) found small to moderate positive effects for changes in dietary behavior, body weight and BMI (Villinger et al., 2019). Surprisingly, the variation in intervention duration (2 weeks to 96 weeks) was not associated with intervention effectiveness (Villinger et al., 2019). These findings are consistent with the meta-analysis by Schippers and colleagues (2017). They found that weight loss was higher in interventions that offered a mix of delivery modes (e.g., email, phone calls) and human contact (Schippers et al., 2017). mHealth interventions targeting physical activity behaviors have also led to significant weight loss (Qin et al., 2022). Other meta-analyses confirm the effectiveness of mHealth interventions on body weight and BMI, but not on physical activity (Islam et al., 2020). A systematic review of

reviews including 55,604 intervention studies found that mHealth interventions resulted in a modest weight loss (Y. Wang et al., 2020). Taken together, mHealth interventions are effective in supporting individuals with overweight and obesity to change health behaviors and reduce body weight at rates comparable to traditional face-to-face approaches. This represents a feasible and accessible complement to in-person weight loss programs.

Despite the benefits and opportunities that mHealth interventions in the field of obesity offer in comparison to and in addition to existing face-to-face treatment strategies, the question of how to achieve sustainable weight loss maintenance remains. As with traditional face-to-face approaches, the sustainability of these intervention effects is not well understood yet. In their systematic review of systematic reviews, Kupila and colleagues (2023) show that the long-term effect of digital interventions on weight loss maintenance is understudied and the existing evidence is inconsistent. There is a lack of high-quality RCTs and systematic reviews that evaluate the long-term effectiveness of mHealth interventions for weight management (Chew et al., 2022; Hutchesson et al., 2021; Schippers et al., 2017).

One aspect that predicts the sustainability of physical and psychological treatment effects is that users repeatedly and continuously engage with the mHealth solution, i.e., adhere to an intervention (Donkin et al., 2011). However, both real-world and trial data suggest that user engagement and adherence (e.g., number of logins, number of modules completed) are low for app-based mobile interventions, with an average attrition rate of 19% (range 0 - 72%; Villinger et al., 2019). To address this challenge, individualization of mHealth interventions has received considerable attention in recent years (K. Ryan et al., 2019; Tong et al., 2021). Offering individualized features and tailoring content to the preferences and needs of specific target groups is considered a promising approach to increase the effectiveness, user engagement, and acceptability of mHealth interventions (Lyzwinski et al., 2018a).

1.4.3 Sex/gender as an Example for Individualization in mHealth

In recent years, there has been great interest in investigating tailored or individualized mHealth interventions in the context of behavior change (Davis et al., 2020; Lau et al., 2020; K. Ryan et al., 2019; Tong et al., 2021). It is proposed that tailored/individualized versus generic digital health interventions contribute to higher rates of engagement and treatment satisfaction, promote adherence, improve clinical outcomes (e.g., increase physical activity and weight loss), and increase cost-effectiveness (Davis et al., 2020; Lau et al., 2020; K. Ryan et al., 2019). In the existing literature, the terms individualization, tailoring, targeting, personalization, and precision health are used interchangeable (P. Ryan & Lauver, 2002). Tailored interventions are

defined as interventions “designed to address the individual characteristics of [a] person within a sample” (Beck et al., 2010; p. 104). Ryan and colleagues define tailoring as “a process whereby the provision of information, advice and support is individualized to the user” (K. Ryan et al., 2019, p. 3). There are many characteristics that can be used as a basis for individualization. For example, personal factors, goals, needs, risk level for a particular disease, health literacy, sociodemographic factors such as age, gender, or socioeconomic status. The degree of tailoring moves along a continuum from personalized (e.g., inserting a person's name into a standard message) to highly tailored content (e.g., customizing content for each individual; Noar et al., 2011). The goal of tailoring interventions is to address salient characteristics of an individual or specific group (Beck et al., 2010) and to increase the acceptability of and responsiveness to an intervention.

There are different approaches to developing, implementing, and evaluating an individualized intervention. Beck and colleagues (2010) propose a framework for developing such an intervention. First, the selection of individual characteristics for tailoring must be defined (e.g., age, gender, diagnosis, preferences, needs, cognitive level, ethnicity/race, beliefs, disease state, resources, physical health status, mental health status, socioeconomic status, stressful life events). In defining the target characteristics of the target group, researchers should be guided by existing evidence on the relationship between the characteristics and treatment outcome (e.g., adaptation of emotional eating intervention components in relation to sex/gender). The second step is to decide how to assess the individual characteristics of each user (i.e., self-administered in surveys, or passive data collection). Step 3 involves processing this information, implementing the tailoring features and defining the rationale for tailoring (Beck et al., 2010). In digital interventions, the selection of content (e.g., recommendations, text, audio) is based on algorithms and decision rules (i.e., computer tailoring) or by a user themselves (i.e., human tailoring; K. Ryan et al., 2019). Subsequently, the intervention needs to be piloted (step 4) and refined (step 5). In the latter, focus groups and interviews with users should be conducted to better understand the impact and acceptability of the intervention. In the final step, the intervention is tested in an RCT and compared with a standard intervention without individualization features. Researchers need to consider what outcomes to assess and whether it is necessary to assess tailored outcomes.

Individualized interventions hold great promise for the treatment of obesity. Considering the multifactorial causes of obesity and overweight, international and national societies recognize that the prevention and treatment of obesity must be individualized and

tailored to the needs of the individual (Durrer Schutz et al., 2019; Semlitsch et al., 2019). Ryan and colleagues (2019) conducted a systematic review examining whether tailored internet-based interventions are more effective for weight loss in individuals with overweight or obesity. The analysis included six interventions tailored by age, weight goal, daily caloric intake, place of residence, and weight loss attempts. Participants were generally positive disposed toward the tailoring approach, with four of these six interventions resulting in greater weight loss than either the active or inactive control (K. Ryan et al., 2019). Further reviews of RCTs strengthen the notion that personalized electronic health (eHealth) interventions can increase the effectiveness of weight loss programs (Lau et al., 2020). However, evidence on the specific effectiveness of mobile-based tailored interventions is lacking. To date, individualization has been based on various sociodemographic or cultural aspects related to the experience, management, and treatment of obesity (K. Ryan et al., 2019). Although sex/gender differences and similarities have been identified in many obesity-related psychosocial factors (e.g., emotional eating, psychosocial burden, treatment expectations and preferences), these aspects have only been considered in limited psychological mHealth interventions.

One of the few digital psychotherapeutic weight-loss interventions to date that considers sex is the intervention by Young and colleagues (2021). The self-guided digital intervention focused on modifying depressive symptoms in men with overweight and obesity. Most of the content was tailored to appeal to men (e.g., male-specific imagery). Results from an RCT showed that the intervention led to reductions in both weight and depressive symptoms at post-treatment and 6-month follow-up (Young et al., 2021). This study provides evidence that online interventions can engage men with overweight and obesity and improve their physical and mental health. Because there are many subpopulations and sex/gender are not an either/or proposition (Hyde et al., 2019), transition from gender-neutral or sex/gender-specific to gender-sensitive digital intervention approaches that address the needs of both men and women (M. Urban, 2021). Opozda and colleagues (2024) note that most psychotherapeutic eHealth interventions to date have been "gender blind", not designed to take into account the characteristics, needs, desires, and circumstances that women and men consider important.

The findings described so far suggest that the identification and modification of cognitive and emotional processes are important considerations in the treatment of obesity, and that the effectiveness of such psychological interventions may be further enhanced if individual needs are more systematically addressed through tailored mHealth approaches. Sex/gender is one promising characteristic to focus on in individualized mHealth interventions (A. J. Cooper

et al., 2021). As described in Chapter 1.3.3, there are observed sex/gender differences in needs, treatment preferences, attitudes and treatment-seeking behavior that are thought to be rooted in gender roles and socialization (Hyde et al., 2019). The development of gender-sensitive interventions on this basis could be promising (Celik et al., 2011) as it improves scientific rigor, fosters innovation, and reduces health disparities (Tannenbaum et al., 2019). The goal of gender-sensitive interventions is to address the different needs, requirements, circumstances, and opportunities of female and male participants in a psychological weight-loss intervention, without reinforcing or assigning gender roles based on biological sex.

1.5 Research Questions

The general introduction to this dissertation has identified some meaningful research gaps and shortcomings in the existing literature of mHealth assessment and intervention studies in the psychological treatment of individuals with overweight and obesity. In summary, research to date suggests that the integration of cognitive and emotional processes in obesity treatment plays a key role in changing weight-related behavior (i.e., eating behavior and physical activity) and thereby increasing the sustainability of weight loss. The effectiveness of face-to-face psychological interventions in clinical routine has been positively evaluated. However, individual and structural barriers make individualized psychological treatment inaccessible to many. This gap can be closed by harnessing the potential of mHealth solutions. Digital approaches allow broader and more independent access and can be tailored to individual needs and preferences in relation to the characteristics of the user (i.e., gender). Research suggests that key health behaviors for weight management, such as physical activity and eating behavior, can be assessed in daily life using digital solutions and modified through multimodal mHealth interventions. Current challenges in this area of research include promoting the uptake and use of these digital solutions and developing mHealth interventions that enable sustainable behavior. Based on current evidence, it can be assumed that digital solutions in the treatment of overweight and obesity are more likely to be accepted, used and lead to sustainable behavior change if psychological aspects, individual preferences, and gender aspects are taken into account.

The overarching aim of this dissertation is to refine the focus on individualized and psychological mHealth solutions implemented within assessment and intervention research for individuals with overweight and obesity. To this end, the body of this dissertation consists of

four chapters with four studies, each contributing to filling the identified research gaps. The specific objectives and research questions are as follows.

To identify mechanisms that could be targeted by mHealth interventions in the long term, assessment studies are needed that examine inter- and intra-individual associations between behavioral, cognitive, and emotional processes in individuals with overweight and obesity in everyday life. Here, EMA has emerged as the method of choice. In relation to physical activity behavior, there is evidence that there is a bi-directional relationship between affect and daily physical activity in individuals with normal weight, and that changes in physical activity are influenced by changes in affect. **Study 1** (presented in Chapter 2) investigated the occurrence of this bi-directional relationship between affect and daily physical activity in a sample of individuals with overweight and obesity. To gain a deeper understanding of the basic mechanisms, a 7-day EMA study (n = 157, 68% female, BMI: 32.99±3.78 kg/m^2) was conducted using accelerometer-derived physical activity counts continuously measured in everyday life. The empirical data for this EMA study was collected within the baseline assessment of the I-GENDO trial at the University of Bamberg and the LWL-University Hospital of the Ruhr-University Bochum between December 2019 and August 2020.

Research Question 1: *Is there a bi-directional association between core affect (i.e., valence, energetic arousal, and calmness) and physical activity levels change in individuals with overweight and obesity at the within- and between-level?*

Evidence from assessment studies suggests that it is promising to modify the underlying emotional and cognitive processes that influence health behavior in everyday life. Furthermore, gender differences have been found in these emotional and cognitive processes, as well as in the perceptions of obesity, treatment needs and expectations. Incorporating these psychological and gender aspects into treatment approaches could improve their acceptability and effectiveness. mHealth interventions allow for such individualized needs and life realities to be taken into account. To date, there are few mHealth interventions that technically implement gender-based individualization. In response to the need for remotely delivered support, we developed the self-guided, individualized, gender-sensitive mHealth intervention I-GENDO, which focuses on changing the emotional and cognitive processes associated with health behavior change and weight loss. **Study 2** (presented in Chapter 3) investigated how the novel intervention design of I-GENDO was accepted and the gender-sensitive features were used by individuals with overweight and obesity. To address these questions, the 12-week long I-

GENDO intervention was evaluated with regard to the feasibility of the gender-sensitive tailoring features, usage patterns, and acceptance. For this study, usage data of the participants of the intervention group (n = 116, 66% female, BMI: 33.58±3.79 kg/m^2) was analyzed. App usage data was collected from January 2020 to November 2020.

Research Question 2: *How did the participants use and accept the psychological mHealth intervention I-GENDO and how did they use the gender-sensitive tailoring features of the intervention?*

Study 3 (presented in Chapter 4) tested the effectiveness of the I-GENDO mHealth intervention in changing eating behavior (i.e., emotional eating, external eating, restrained eating), physical activity levels, and BMI in individuals with overweight and obesity within a 15-month RCT (n = 213, 67% female, BMI: 33.35±3.79 kg/m^2). Measurements were conducted at baseline, at 3 months (post-intervention), 9 months, and 15 months post baseline. Data was collected from December 2019 to November 2021.

Research Question 3: *How did using the psychological mHealth intervention I-GENDO affect changes in eating behavior (i.e., emotional eating, restrained eating, and external eating), physical activity and BMI over 15 months?*

Studies 1 to 3 demonstrate the potential of using mHealth in the area of overweight and obesity. However, there are challenges in developing, evaluating, and delivering digital assessment and intervention solutions, such as low adherence and a lack of high-quality evidence. As the field continues to evolve, it is especially important to synthesize knowledge from development and evaluation processes to improve user experience and methodological quality. Therefore, guidelines for researchers and practitioners were developed based on the experiences and lessons learned from the development and evaluation of digital assessment and intervention approaches for overweight and obesity presented in Studies 1 to 3, as well as current literature in the field of e-mental health. **Study 4** (presented in Chapter 5) presents these guidelines for researchers and practitioners in a more comprehensive consensus statement that summarizes existing evidence and provides recommendations for the development, implementation, and evaluation of digital assessment and intervention studies. Twenty-five international researchers in the field of e-mental health contributed to this consensus based on an adapted Delphi process, providing an overview of their knowledge, the current state of the literature, and practical recommendations on relevant topics in e-mental health assessment and

intervention. The final objective of this dissertation is to describe how the development process, acceptance, use, and effectiveness of the digital assessment and intervention solutions implemented in Studies 1 to 3 informed the development of these guidelines and to draw conclusions for further assessment and intervention studies in the context of overweight and obesity.

Research Question 4: *What conclusions can be drawn from the current state of knowledge regarding the acceptance, use and effectiveness of future digital solutions for the assessment and treatment of overweight and obesity?*

The four original studies (Figure 1) will be presented in the following four chapters. **Study 1** assessed the bi-directional association between affect and physical activity in individuals with overweight and obesity (Chapter 2). **Study 2** describes the development, acceptability, and usage of the individualized gender-sensitive psychological mHealth intervention I-GENDO (Chapter 3). **Study 3** presents the evaluation of the I-GENDO mHealth (Chapter 4), and **Study 4** proposes a guideline for researchers and practitioners on how to develop, conduct and evaluate mHealth assessment and intervention studies in the context of e-mental health (Chapter 5).

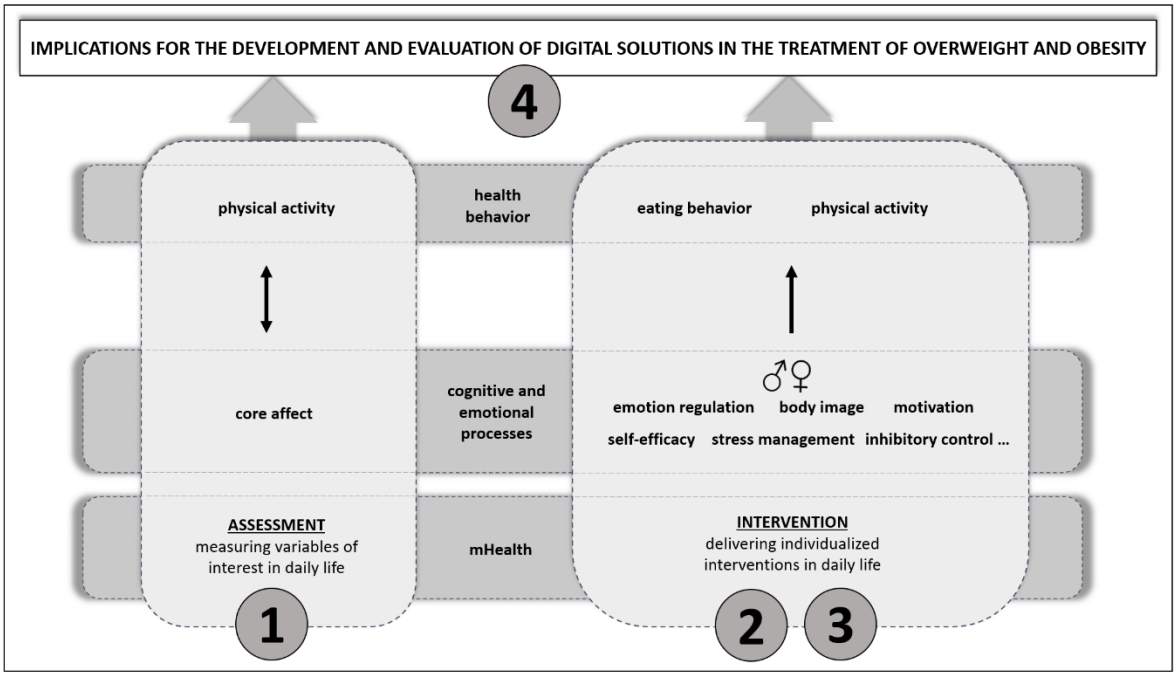

Figure 1. Integration of the original studies into the theoretical background. *Note*. Numbers (1-4) are equivalent to the number of the original studies 1 to 4.

Chapter 2 | Study 1: Bi-directional Associations of Core Affect and Physical Activity in Adults with Higher Body Weights: An Ecological Momentary Assessment Study

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The following article was first published in *Journal of Health Psychology*

Seiferth, C.*, Fiedler, J.*, Färber, T., Pape, T.., Schroeder, S., Herpertz, S., Steins-Loeber, S., Wolstein, J. (2024). Bi-directional Associations of Core Affect and Physical Activity in Adults with Higher Body Weights: An Ecological Momentary Assessment Study. *Journal of Health Psychology*, *29*(10). 1115-1128. https://journals.sagepub.com/doi/full/10.1177/13591053241228202

Full length article

JHP

Journal of Health Psychology
2024, Vol. 29(10) 1115–1128

DOI: 10.1177/13591053241228202
journals.sagepub.com/home/hpq
Sage

Bi-directional associations of core affect and physical activity in adults with higher body weight: An ecological momentary assessment study

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Abstract

Affect is known to be predictive of and enhanced by higher physical activity (PA) levels in the general population. This secondary analysis aimed to increase the understanding of the bi-directional relationship between PA and core affect (i.e. valence, energetic arousal, and calmness) among adults with higher body weight. Affect and PA were assessed in naturalistic settings via ecological momentary assessment using a mixed sampling scheme from 157 participants (body mass index: $32.99 \pm 3.78\,kg/m^2$). Multilevel models revealed that being more physically active in the 15 minutes prior to the assessment predicted an increase in energetic arousal and a decrease in calmness. Subsequently, feeling more energetic and agitated was associated with increased PA within the following 15 minutes. Valence (i.e. pleasure–displeasure) was not associated with PA nor predictive of subsequent PA. Digital PA interventions may target the enhancement of feelings of energy and present psychoeducation about these distinct psychological benefits.

Keywords

accelerometry, affective states, ambulatory assessment, vector magnitude, obesity

Background

Being physically active on a regular basis in everyday life is linked to physical and mental health benefits for individuals with higher body-weight (Carraça et al., 2021; Oppert et al., 2023). However, research suggests that fewer higher-weight individuals are likely to achieve sufficient physical activity (PA) levels compared to "normal-weight" counterparts (Cassidy et al., 2017; Ladwig et al., 2021). Hence recognizing

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dynamic real-life facilitators or barriers to increase PA in everyday life is important for identifying targets for PA promotion in obesity management.

Affect has been highlighted as a meaningful predictor and outcome of PA in the general population (Bryan et al., 2017; Conroy and Berry, 2017; Ekkekakis and Brand, 2019; Forster et al., 2021; Reed and Ones, 2006; Stevens et al., 2020; Williams and Evans, 2014). The hedonic theory proposes that a positive affective response (i.e. feeling good) during or following PA is associated with a higher likelihood to repeat the behavior and thus engage in more structured (Bryan et al., 2017; Conroy and Berry, 2017; Emerson and Williams, 2015; Lyubomirsky et al., 2005; Rhodes and Kates, 2015) and incidental activity (e.g. walking, cleaning; Le et al., 2022). Additionally, increased PA can lead to positive affective outcomes indicating a dynamic bidirectional relationship (Emerson and Williams, 2015; Hyde et al., 2011) which has been replicated at different time intervals in intensive longitudinal studies in healthy children, adolescents, and adults (e.g. Bourke et al., 2021; Kim et al., 2020; Liao et al., 2015, 2017; Ruissen et al., 2022).

Affect can be conceptualized as core affect, which is defined as a "neurophysical state consciously accessible as a simplest raw (nonreflective) feeling evident in moods and emotions" (Russell, 2003: 148). Across the literature, there is an ongoing discourse about how to conceptualize and measure core affect (Ekkekakis, 2013; Williams et al., 2019). Based on the circumplex model of core affect (Russell, 1980), affect can be summarized along two independent dimensions of valence (i.e. pleasure–displeasure) and arousal (i.e. activation–deactivation). Thayer (1990) rejected valence as a separate dimension and claimed that two distinct types of arousal exist: energetic arousal (i.e. tiredness–wakefulness) and tense arousal (i.e. relaxation–tension). In contrast, the two-dimensional approach from Watson and Tellegen (1985) described affect along the dimensions of positive affect (e.g. happiness, excitement, alertness) and negative affect (e.g. distress, anger, fear). A three-dimensional model based on valence, energetic arousal, and calmness (Schimmack and Grob, 2000; Schimmack and Rainer, 2002) has been proven to be sensitive enough to measure fluctuations of core affect within-person in daily life (Wilhelm and Schoebi, 2007) and is used in this paper.

Existing studies that investigate the dynamic relation between dimensions of core affect and incidental PA in everyday life usually use ecological momentary assessment (EMA). EMA allows to assess near real-time data and thus limit retrospective bias, improving ecological validity by assessing the data in everyday life, and to disentangle within- (i.e. how a person's associations between core affect and PA change within this person over minutes, days, or weeks) and between-person (i.e. how associations differ between persons with higher average core affect/PA from persons with lower average core affect/PA) associations (Kanning et al., 2013; Liao et al., 2016). Such intensive longitudinal assessments allow measuring detailed and temporal variations between affect and PA, which are possible reasons for physical inactivity in everyday life.

Despite the benefits mentioned above, most of the studies investigating the relationship between core affect and PA in higher bodyweight individuals to date have been conducted in laboratory settings and focus on structured PA sessions and between-person effects (e.g. Berger et al., 2023; Ekkekakis et al., 2010; Ekkekakis and Lind, 2006; Hulens et al., 2003; Unick et al., 2012, 2015). Moreover, a range of negative emotional experiences that may influence the relationship between affect and PA in individuals with higher body weight have been identified (Baillot et al., 2021; Hamer et al., 2021; Thedinga et al., 2021). The combination of psychological (e.g. fear of embarrassment and weight discrimination, internalized weight stigma, lower self-efficacy) and physical (e.g. discomfort, perceived pain) distress may be a determinant for decreased PA engagement in this group (Ekkekakis et al., 2016).

However, these results provide little information about how affect and PA are related in real-life among adults with higher body-weight.

To deepen this understanding, EMA studies are needed that examine the nature and frequency of time-varying within-person associations between core affect and device-based PA (Engel et al., 2016). Previous EMA studies have investigated this reciprocal relationship at the day-level and found significant within-person associations between PA and valence (Carels et al., 2007; Emerson et al., 2018) and negative affect (Kerrigan et al., 2020).

Although the understanding of the temporal dynamics of bidirectional within-person associations is inconclusive (Kim et al., 2020), core affect is thought to change rapidly within-persons (Brose et al., 2020) and that the association between affect and PA is predicted to be greatest during or immediately after PA (Reichert et al., 2017). It is therefore essential to investigate the magnitude of the effect within shorter timeframes to gain a deeper understanding about the timing of the affect-PA relation in a sample of higher-weight individuals. Such momentary associations have been primarily evaluated in the general population analyzing short time windows of PA in the 10 or 15 minutes before and following an EMA (Bossmann et al., 2013; Kanning et al., 2015; Liao et al., 2017; Reichert et al., 2017). More PA was associated with higher valence (Bossmann et al., 2013; Liao et al., 2017; Schwerdtfeger et al., 2010) and higher energetic arousal (Bossmann et al., 2013; Kanning et al., 2015; Liao et al., 2017; Reichert et al., 2017) and vice versa (Kanning and Schoebi, 2016; Koch et al., 2018; Liao et al., 2017; Reichert et al., 2016). Concerning calmness, bidirectional associations between higher PA and lower calmness were identified (Kanning et al., 2015; Koch et al., 2018; Liao et al., 2017; Reichert et al., 2016, 2017).

Building on the above findings, the current EMA study aimed to investigate the bidirectional association between estimates of PA and dimensions of core affect (i.e. valence, energetic arousal, and calmness) in a sample of higher-weight individuals at the within- and between level using accelerometer-derived PA counts continuously measured in everyday life over seven consecutive days. The first objective of this secondary analysis was to examine whether PA in the *15 minutes prior* to the EMA is associated with participants reports of core affect at the within-person levels. We hypothesized that higher levels of PA *15 minutes prior* to an affect measurement occasion would be associated with higher reported levels of valence (H1.1) as well as energetic arousal (H1.2) and lower reported levels of calmness (H1.3). The second objective was to investigate whether participants' reports of core affect would be associated with PA in the *following 15 minutes* at the within-person levels. We hypothesized that higher levels of valence (H2.1) and energetic arousal (H2.2) and lower levels of calmness (H2.3) at one EMA would be associated with higher levels of PA in the *following 15 minutes*. We further explored differences at the between-person level and controlled for both person-specific (sex, age, BMI) and study-related variables (day of the week, time of the day, day in the study).

Methods

This is a pre-registered secondary analysis of existing EMA data from a randomized controlled trial (RCT) that tested the effectiveness of the gender-sensitive mHealth intervention I-GENDO (Pape et al., 2022; Seiferth et al., 2023).

Participants and procedure

Participants were recruited via social media, newspaper, radio, and self-help groups from December 2019 to August 2020. Eligible individuals (Additional File 1) initially attended an in-person appointment at the study sites to receive an accelerometer and the login information for the I-GENDO application. The design of the original RCT was that participants completed a 7-day assessment (data collection: December 2019 to August 2020), followed by a 12-week intervention period and a second 7-day assessment. The follow-up assessments took place 9 and 15 months after study inclusion. Participants were informed of their group

allocation after the first 7-day assessment was completed. For the current examination, only data from those participants who participated in the first assessment and who both wore the accelerometer and answered at least one EMA questionnaire were included ($n = 196$, 68% female). Participants received a monetary compensation of 10€ for each day with at least 10 hours accelerometer wear-time and 30€ for completing the first questionnaire of the RCT.

EMA data collection procedure

A mixed sampling scheme with both semi-random signals and participant-initiated prompts was applied. Participants chose their preferred time frame of assessment (e.g. 7 a.m.–10:30 p.m), which could be adapted during the 7-day assessment. Participants were alerted by the app at random times within eight 90-minute blocks that were 30 minutes apart throughout the chosen time period.

Participants were instructed to respond to the prompt as soon as possible in everyday life. EMA questionnaires consisted of 18 items in total with an estimated response time between 30 and 120 seconds. Only the items measuring core affect were included in this examination. For these items, participants marked the point that represented their perception of their current state on a visual analog scale. If participants missed a prompt or were not able to answer the questions at the moment, they were able to postpone the questions. Participants were not aware of the prompting schedule and were only informed that prompts would occur randomly in the chosen time span. Participants' compliance with the sampling schedule was calculated from the completed number of assessments relative to the 56 scheduled assessments.

Measurements

Questions about age, sex, height, and weight were included in the questionnaire of the RCT. BMI was calculated by dividing the reported weight in kilograms by height in meters squared.

Device-based measured PA. PA in everyday life was measured continuously using the tri-axial ActiGraph® wGT3X-BT accelerometer (firmware v1.9.2, ActiGraph, Pensacola, FL, USA). The accelerometers have shown good validity and reliability in adults in previous studies (Aadland and Ylvisåker, 2015). Participants were instructed to position the sensor at the right hip, which was found to be a good placement for the assessment of everyday PA (Cleland et al., 2013) and to wear the accelerometer during waking hours and to only take it off while showering or participating in other water-related activities. PA as measured by the accelerometer was expressed as vector magnitude (VM) of 60-second epochs, which combines the mean acceleration from three individual axes $\left(vm = \sqrt{\left(axis\ 1^2 \right) + \left(axis\ 2^2 \right) + \left(axis\ 3^2 \right)} \right)$. VM was choosen over certain intensity estimations like moderate-to-vigorous PA for better comparability throughout studies as for example, the choice of certain cut-points varies greatly throughout the literature (Burchartz et al., 2020). VM represents a dimensional estimate for PA over a defined time period (Migueles et al., 2022) and is used for estimating energy expenditure expressed as metabolic equivalents (MET) and intensity classification from cut points (Sasaki et al., 2011). Notably, cut points for energy expenditure in higher-weight adults based on walking have been reported as 3454–7555 vm counts min^{-1} for moderate PA (3–6 METs) and >7555 vm counts min^{-1} for vigorous PA (>6 MET) (Howe et al., 2017).

Core affect. To assess core affect, the German short scale of the Multidimensional Mood Questionnaire (Steyer et al., 1997), developed and validated for momentary assessment (Wilhelm and Schoebi, 2007), was used. The scale consists of six bipolar items reflecting three basic dimensions of core affect: valence (unwell–well, discontent–content), energetic arousal (tired–awake, without energy–full of energy), and calmness (tense–relaxed, agitated–calm). The score for each subscale is the mean

of the two item scores and ranges from 0 (lowest) to 100 (highest).

Data analysis

Raw PA data was imported into the ActiLife® software (v6.13.4; ActiGraph, Pensacola, FL, USA; Additional File 1). PA data was matched with the EMA questionnaire responses using electronic date and time stamps within a Microsoft Access database. Following existing EMA studies we included PA in the *15 minutes prior* to and *15 minutes following* the affect assessment. This measurement interval was also chosen for methodological reasons, as the EMA was scheduled to be at least 30 minutes apart, thus preventing the PA data from being considered more than once. Proceeding from the time stamps of the questionnaire (i.e. opening and completion), PA was calculated by aggregating the mean VM from *15 minutes prior* to (i.e. 15 minutes before the questionnaire was opened) and *15 minutes following* (starting from the time the questionnaire was completed) each completed EMA (Additional File 1). EMA/PA data, participant data (i.e. age, sex, BMI), and time variables (i.e. weekend/weekday, time of the day, day in the study, time from beginning of the study) were merged.

Statistical analysis

R (R Core Team, 2021) and RStudio (RStudio Team, 2021) were used for all analyses (Additional File 1). Multilevel models were calculated with the repeated measurements (level 1) nested within participants (level 2). Four separate models were calculated to investigate the influence of PA in the *15 minutes prior* to the EMA on affect (H1.1–1.3) as well as the influence of affect on PA in the *15 minutes following* the assessment (H2.1–2.3).

All continuous predictors (PA in the *15 minutes prior*, valence, calmness, energetic arousal), were centered at the person-mean (Hoffman and Stawski, 2009) and included into the respective models at level 1 as fixed effects. Random effects for each predictor were included in the model. Non-significant random effects were excluded, resulting in different models for the predictors. Next, we entered a series of variables at level 1 as fixed effects to control for timely and diurnal variations (Additional File 1). PA in the *15 minutes prior* to the prompt was added as a control variable at level 1 for the PA model. The person-mean of the respective predictor and sex, BMI (kg/m^2), and age in years were added at level 2 into the models. Variables were only included in the final models if they improved the model-fit (Additional File 1). Level for significance was set a priori to $\alpha < 0.05$.

Results

Participant's characteristics and the mean of the predictor and outcome variables are shown in Table 1. Attrition rates are displayed in Additional File 2.

Affect following physical activity

Within-person results indicate no significant relationship between PA and valence (Table 2). As hypothesized, PA was associated with higher energetic arousal ($\beta = 0.08$, $p < 0.001$) and lower calmness ($\beta = -0.04$, $p = 0.035$) within-persons. A 1-point increase in PA above the person-mean in the *15 minutes prior* the assessment of affect was related to an average increase of 0.0027 higher energetic arousal, and a decrease of −0.0012 calmness. Between-person results showed a significant effect between PA and energetic arousal ($\beta = 0.10$, $p = 0.014$), indicating that participants with higher PA than the average person show higher values of energetic arousal (Additional File 2).

Physical activity following affect

Within-person results indicated no significant relationship between PA and valence (Table 3). As hypothesized, energetic arousal was associated with higher PA in the *following 15 minutes*

Table 1. Descriptive data of all participants and observations included in the analysis.

	Female ($n = 107$)		Male ($n = 50$)	
Age in years, *M* (SD)	47.0 (12.9)		51.0 (9.5)	
Body mass index, *M* (SD)	33.2 (3.7)		32.4 (3.9)	
	15 minutes prior	15 minutes following	15 minutes prior	15 minutes following
Vector magnitude, *M* (SD)	765 (772)	628 (736)	762 (873)	669 (809)
Valence, *M* (SD)	68.5 (24.5)	68.6 (24.6)	74.4 (23.3)	74.4 (23.5)
Energetic arousal, *M* (SD)	56.8 (26.9)	57.6 (26.7)	66.7 (25.5)	67.6 (25.2)
Calmness, *M* (SD)	64.9 (25.2)	64.6 (25.2)	68.7 (25.7)	68.5 (26.0)

Displayed are the means (*M*) and standard deviations (SD) for the parameters age and body mass index, as well as the mean and standard deviations of the 7-day assessment of the variables vector magnitude, valence, energetic arousal, and calmness separated by sex (female and male) and time period (15 minutes prior and 15 minutes following). A total of $N = 157$ participants and $n = 4807$ observations (15 minutes prior to the assessment) and $n = 4276$ observations (15 minutes following the assessment) were included in the analysis.

($\beta = 0.09$, $p < 0.001$) and lower calmness ($\beta = -0.05$, $p = 0.007$) within-persons. A 1-point increase in energetic arousal and calmness above the person-mean was associated with an average increase of 3.01 higher, and 2.03 lower PA during the *following 15 minutes*.

Discussion

The primary aim of the present secondary analysis was to investigate the bi-directional association between device-based measured PA and self-reported levels of valence, energetic arousal, and calmness in everyday life in a sample of individuals with higher body weight on the within-person level. The findings support the hypothesis of a bi-directional association between PA in daily life and energetic arousal (H1.2, H2.2) and calmness (H1.3, H2.3), whereas no evidence was found for valence (H1.1, H2.1).

This null finding for valence is unexpected because from a theoretical perspective, positively valenced affect is assumed to influence the cognition, perception, and behavior of individuals insofar that beneficial resources are expanded and positive goals (i.e. health promotion) are pursued (Lyubomirsky et al., 2005; Williams and Evans, 2014). According to Fredrickson (2001), this broaden and built state is needed to prepare oneself for future challenges. In the other direction, PA is assumed to be associated with the release of mood-enhancing neurotransmitters (i.e. serotonin) and protective effects on the stress-regulation system (Basso and Suzuki, 2017). These theoretical assumptions are strengthened by prior EMA studies investigating the reciprocal relationship between PA and valence in non-clinical samples as well as in individuals with higher body weight across varying time frames (Carels et al., 2007; Emerson et al., 2018; Liao et al., 2015). An explanation for the deviating results could be the wide variety of study designs and assessments of affective valence used (Kim et al., 2020). Emerson et al. (2018) found bi-directional associations between more positive valence and higher PA at the day level. In this study, different measures for PA (i.e. self-report) and affect (i.e. feeling scale) were used which might explain the different results (Silveira et al., 2022). Another reason could be that the positive effect of PA on valence and vice versa might hold over the course of the day in higher-weight individuals but not immediately as shown in the general population (Bossmann et al., 2013; Williams et al., 2012). Our findings are comparable to those of Kanning et al. (2015), who also found that PA in the 10 minutes prior did not predict valence in older adults. Interestingly, they found that the relationship was moderated by BMI, indicating that individuals with higher BMI scores were more

Table 2. Multilevel model examining the influence of physical activity on valence, energetic arousal, and calmness.

	Valence					Energetic arousal					Calmness				
	B	β	95% CI	Std. 95% CI	*p*	*B*	β	95% CI	Std. 95% CI	*p*	*B*	β	95% CI	Std. 95% CI	*p*
Intercept	64.47	−0.02	57.81–71.13	−0.11 to 0.07	<**0.001**	56.73	−0.00	50.34–63.11	−0.08 to 0.07	<**0.001**	59.68	−0.01	52.40–66.95	−0.10 to 0.08	<**0.001**
VM (within)	0.0004	0.01	−0.0007 to 0.0014	−0.02 to 0.04	0.503	0.0027	0.08	0.0019–0.0035	0.05–0.10	<**0.001**	−0.0012	−0.04	−0.0024 to −0.0001	−0.07 to −0.00	**0.035**
VM (between)	0.0036	0.04	−0.0046 to 0.0117	−0.05 to 0.13	0.388	0.0097	0.10	0.0020–0.0174	0.02–0.17	**0.014**	0.0008	0.01	−0.0080 to 0.0096	−0.08 to 0.10	0.856
Weekday/weekend	3.66	0.07	2.38–4.94	0.04–0.09	<**0.001**						4.99	0.09	3.68–6.30	0.06–0.11	<**0.001**
Sex	5.60	0.11	0.82–10.38	0.02–0.20	**0.022**	9.69	0.17	5.17–14.22	0.09–0.25	<**0.001**	5.33	0.10	0.22–10.45	0.00–0.19	**0.041**
Age (in years)	0.21	0.10	0.02–0.39	0.01–0.20	**0.028**	0.24	0.11	0.07–0.42	0.03–0.19	**0.007**					
Afternoon						−5.30	−0.09	−6.88 to −3.73	−0.12 to −0.07	<**0.001**	1.66	0.03	0.20–3.12	0.00–0.06	**0.026**
Evening						−15.96	−0.28	−17.56 to −14.36	−0.31 to −0.25	<**0.001**	5.40	0.10	3.92–6.88	0.07–0.13	<**0.001**
Random effects															
σ^2	396.03					488.64					411.53				
τ_{00id}	179.37					155.68					212.71				
τ_{11}	$<0.01_{id.VM}$										$<0.01_{id.VM}$				
ρ_{01}	0.04_{id}										0.01_{id}				
ICC	0.32					0.32					0.35				
N_{id}	157					157					157				
Observations	4807					4807					4807				

Displayed are the within-person results of the person-mean centered variable vector magnitude (VM) 15 minutes prior to the assessment, the control variables weekday/weekend (weekday = 0, weekend = 1), and the dummy coded control variables morning (reference), afternoon, and evening on valence, energetic arousal, and calmness (all scaled 0–100). Additionally, the between-person results of the vector magnitude, sex (0 = female, 1 = male), and the grand mean centered variable age (in years) on valence, energetic arousal, and calmness are shown. All results are displayed using the raw Beta (B), the standardized Beta (β), 95% confidence intervals (CI), and standardized (std.) 95% CI. Additionally, the within-person variance (σ^2), the between-person variance (τ00 id), (τ11), (ρ01), the intraclass correlation coefficient (ICC), the number of participants (Nid), and the number of observations are displayed. Bold font reflects statistically significant effects.

Table 3. Multilevel model analysis examining the influences of valence, energetic arousal, and calmness on physical activity.

	Vector magnitude (15 minutes following)				
	B	β	95% CI	Std. 95% CI	*p*
Intercept	481.35	−0.01	298.61–664.08	–0.06 to 0.05	<**0.001**
Valence (within)	0.64	0.02	−1.12 to 2.41	−0.03 to 0.06	0.477
Energetic arousal (within)	3.01	0.09	1.95–4.07	0.06–0.12	<**0.001**
Calmness (within)	−2.03	−0.05	−3.50 to −0.56	−0.09 to −0.02	**0.007**
VM 15 minutes prior	0.26	0.26	0.21–0.31	0.21–0.31	<**0.001**
Valence (between)	0.04	0.00	−6.39 to 6.47	−0.12 to 0.12	0.991
Energetic arousal (between)	2.66	0.05	−1.28 to 6.61	−0.02 to 0.13	0.185
Calmness (between)	−0.16	−0.00	−5.08 to 4.77	−0.10 to 0.10	0.951
BMI	−11.03	−0.06	−20.80 to −1.25	−0.11 to −0.01	**0.027**
Random effects					
σ^2	450,984.42				
τ_{00id}	40,603.38				
$\tau_{11\ valence\ (within)}$	10.01				
$\tau_{11\ VM\ 15\ minutes\ prior}$	0.05				
ρ_{01}	0.48				
	0.45				
ICC	0.14				
N_{id}	157				
Observations	4276				
R^2/Conditional R^2	0.089/0.215				

Displayed are the within-person results of the person-mean centered variables valence, energetic arousal, and calmness, and the within-person control variable vector magnitude (VM) 15 minutes prior to the assessment on vector magnitude 15 minutes following the assessment. Additionally, the between-person results of person mean valence, energetic arousal, calmness, and grand mean centered BMI. All results are displayed using the raw Beta (B), the standardized Beta (β), 95% confidence intervals (CI), and standardized (std.) 95% CI. Additionally, the within-person variance (σ^2), the between-person variance (τ00 id), (τ11 ID.val), (τ11 ID.vm_b15), (ρ01), the intraclass correlation coefficient (ICC), the number of participants (N id), and the number of observations are displayed. Bold font reflects statistically significant effects.

likely to experience higher levels of unpleasantness when they were physically active. These findings combined with our results match the considerations of Ekkekakis et al. (2016) who examined the divergent determinants of exercise in individuals with a BMI greater or equal 25 compared to "normal-weight" counterparts. In their review, they proposed a conceptual framework which describes that the greater the body weight, the more physical and psychological discomfort arises and consequently a decrease in motivation to engage in PA. In comparison to "normal-weight" counterparts, higher bodyweight individuals seem to experience less pleasantness from exercise (Ekkekakis et al., 2016). Based on our results, we assume that even though the perceived consequences of acute everyday activity are unlikely as severe as in the context of structured exercise, the conscious decision to be physically active throughout the day (i.e. getting up at work, taking the stairs) could be rendered by past affective experiences in the context of exercise. Following a dual-process decision making system (Bryan et al., 2017; Hofmann et al., 2008; Williams and Evans, 2014), this process could get impeded by the affect-driven impulsive pathway which relies on interoceptive cues and, does

not distinguish between different forms of movement. If this assumption can be confirmed in further experimental and controlled study designs within comparable samples, time, and PA outcomes, it may provide a possible mechanism for why people with higher body weight show lower levels of everyday activity.

As hypothesized, higher energetic arousal was reported by the participants whenever they were more physically active in the *15 minutes prior* to the assessment (H1.2). The reverse analysis showed that higher energetic arousal was associated with being more physically active in the *15 minutes following* the assessment (H2.2). Comparable results were found in previous studies investigating adults with "normal-weight" and a range of PA outcomes and time frames (Liao et al., 2015; Reichert et al., 2017) as well as for adults with higher body weight that used self-reported measures of PA within one single day (Emerson et al., 2018). These finding are reasonable because behavioral theories assume that positively valenced experiences are more likely to be repeated, thus reinforcing future PA behavior in everyday life (Stevens et al., 2020). However, the finding is particularly interesting in light of the fact that we detected no positive association between valence and PA. In our sample, higher levels of PA led to a high-activation (i.e. feeling awake and full of energy) but not to more pleasantness. To clarify these findings, it would be necessary to assess if other variables, such as the context or the degree of self-determination, are responsible for this association (Kanning et al., 2021). To establish a causal interpretation and inform future PA interventions, a promising approach would be to experimentally modify participants' energetic arousal and analyze the effect on PA. If this association proves to be causal then feeling tired and lacking energy may be a barrier for PA uptake.

We found evidence for a significant negative bi-directional association between PA and calmness. If individuals with higher body-weight were more physically active, they felt more agitated (i.e. less calm and relaxed; H1.3), and if participants felt calmer they were less physically active (H2.3). This finding is consistent with previous EMA studies investigating the influence of calmness in populations with normal weight (Kanning et al., 2015; Reichert et al., 2016, 2017). Reichert et al. (2016) showed that this negative within-person influence is still evident up to 140 minutes. The extent to which PA and calmness are interdependent or if further variables moderate this association is still unclear. It could be, for example, that higher levels of PA are associated with higher levels of stress (Stults-Kolehmainen and Sinha, 2014) (e.g. running to catch a train ride) or internalized weight stigma (Carels et al., 2019) (e.g. walking up stairs while being watched by others). When developing PA interventions, researchers and practitioners should inform participants about the acute effects of PA (i.e. restlessness) and the long-term beneficial effects on well-being. Consideration of the optimal timing of PA is important to improve well-being (i.e. not at the end of the day when levels of calmness tend to be lower) (Kanning et al., 2015).

The strengths of our investigation are that it includes a large sample of the understudied population of higher-weight individuals, combines device-based measured PA with EMA, and follows a pre-registered design (Liao et al., 2016). Nonetheless, some limitations must be considered when interpreting the results of this paper. First, PA data were not distinguished between exercise and non-exercise PA even though previous studies showed distinct associations to core affect (Reichert et al., 2017). Given the limited studies on participants with higher body weight, this study included only the raw measure of activity counts. Future studies should delve deeper and include other PA measures (i.e. light, moderate, and vigorous PA, step count) and contextual variables. Second, participants had unlimited time to respond to the prompts because the program had no time-out feature. Time was accounted for in the data processing, but it led to missing data. Including timeout for prompts could reduce participant burden in future research. Third, time windows of 15 minutes were chosen for the analysis of the bi-directional association of PA and affect

according to previous literature (Bourke et al., 2021; Liao et al., 2017; Schwerdtfeger et al., 2008). Given the insufficient knowledge about the temporal course of these associations, various time windows should be explored in future studies (Kim et al., 2020; Reichert et al., 2016). Fourth, some data collection took place during the COVID-19 pandemic. Because of variations in the timing of the study enrollment and data assessment, we did not systematically examine the potential influence of different restrictions in different regions. Finally, it must be taken into account that no independent power analysis was performed for the present secondary analysis. Future studies should perform simulation-based multilevel power analysis to ensure adequate sample size.

Conclusions

Overall, the results suggest distinct acute bi-directional within-person associations between the dimensions of core affect and PA among adults with higher body weight in everyday life. Although more research is needed to confirm these findings, we suggest two important implications as a starting point for researchers and practitioners that might inform the development and design of (digital) interventions targeting PA engagement.

First, the motivation to engage in long-term everyday PA among higher-weight individuals could be enhanced by delivering health communication messages about the benefits of PA that go beyond the weight-related health outcomes. Psychoeducational material should be provided that highlights the affect-regulation potential of everyday PA. Moreover, our finding that being physically active led to no enhancement in feeling better contradicts the narrative often portrayed in PA programs ("move more and you will feel better"). Hence, this association might not apply as an acute effect to higher-weight individuals and should thus be presented with caution. Such messages could establish a discrepancy between the expectations of PA and the actual experience of PA. Instead, participants' attention should be drawn to feelings of energy and agitation (i.e. psychoeducation and self monitoring after PA engagement), which occur even after short periods of PA and which might increase the adaption of a habitual PA lifestyle.

Second, our results suggest that feeling more energized and agitated predicted acute PA engagement in a sample of higher-weight individuals. These findings could imply that interventions designed to foster PA might be more effective when they deliver brief affect-enhancing strategies that target the modification of energetic arousal and calmness in real-time. Higher-weight individuals might benefit from guided mental imagery tasks about PA engagement or the confrontation with auditory or visual stimuli (i.e. high arousal rhythmic music, positive media content). Additionally, situations in which an individual feels more energetic and less calm might represent an opportune moment for PA interventions (i.e. recommend PA when ratings of energetic arousal are high and ratings of calmness are low). The timing of such personalized acute interventions could be identified by affect focused assessments and the identification of individual patterns of affect fluctuation (i.e. just-in-time adaptive interventions).

Replication of the present evidence on distinct influences of core affect and PA within other (more diverse) samples (i.e. BMI, gender, race, no treatment enrollment) is needed to generalize these findings and confirm causality. Likewise, we encourage further studies to implement experimental approaches (e.g. manipulation of energetic arousal) and to investigate factors that might moderate the nature of the reciprocal associations in individuals with higher body weight (e.g. internalized weight bias, physical limitations, context, intensity of PA, self-determination, self-efficacy, depression).

Acknowledgements

We are very grateful to all participants who took part in the I-GENDO study. Special thanks to groupXS Solutions GmbH for the implementation of the EMA. The authors acknowledge support by the Open Access Publication Fund of the University of Bamberg.

Author contributions

CS and JF formulated the study question, performed the data analysis, data interpretation, generation of

figures, and drafted the manuscript. CS, TF, MP, and SS carried out the ambulatory assessment study and were responsible for the data management. JW was responsible for preparing the accelerometer and electronic diary data for statistical analysis. SS, SH, SSL, and JW made substantial contributions to the conception and study design. All authors read and approved the final manuscript.

Data sharing statement

Protocol, hypotheses, analytic code and datasets generated and analysed during the current study are available on the Open Science Framework, https://osf.io/p6xuf/.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was funded by the Federal Ministry of Education and Research (BMBF) [grant no. 01GL1719A and 01GL1719B] and the Peer-Mentoring Team-Program of the German Psychology Society (DGPs, section Health Psychology).

Ethics approval

The study was carried out in accordance with the Declaration of Helsinki. The Ruhr-University Bochum Institutional Review Board (No. 18-6415) as well as the ethics committee at the University of Bamberg approved this study.

Informed consent

All participants were informed about the study and provided written consent.

Pre-registration

The I-GENDO study was pre-registered at ClinicalTrials.gov, NCT04080193, date: 2019-09-06, https://clinicaltrials.gov/ct2/show/NCT04080193 and at Open Science Framework, date: 2021-09-10 https://osf.io/p6xuf/.

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Supplementary Material

Manuscript: Bi-directional associations of core affect and physical activity in adults with overweight and obesity – An ecological momentary assessment study

Additional File 1

- **Table S1.** Eligibility criteria of the study.

Inclusion Criteria	Exclusion Criteria
• ≥18 years of age • Obesity class I or II (30.00 - 39.99 kg/m^2) with subjectively experienced weight-related impairment OR • Overweight (25.00 - 29.99 kg/m^2) with weight-related health problems and/or visceral adipose tissue and/or high psychosocial weight-related distress • Current motivation to lose weight • Access to a smartphone	• Current (or within the last 12 months) involvement in a structured weight loss intervention or psychotherapeutic treatment of weight-related health problems • Previous or intended bariatric surgery • Current pregnancy • Current intake of drugs that influence weight • Current substance abuse, major depression, suicidal ideation • Severe cognitive impairments • Insufficient knowledge of the German language • Binge eating disorder or bulimia nervosa • Insulin-dependent type 1 diabetes • Cancerous disease within the last 5 years

- **Deviations from the pre-registration**

In contrast to the pre-registration, we explored no further time-dependent associations by specifying additional models with shorter time intervals of physical activity (e.g., 5 and 10 min) for a more concise focus.

- **Explanatory notes regarding the device measured physical activity and data preprocessing**

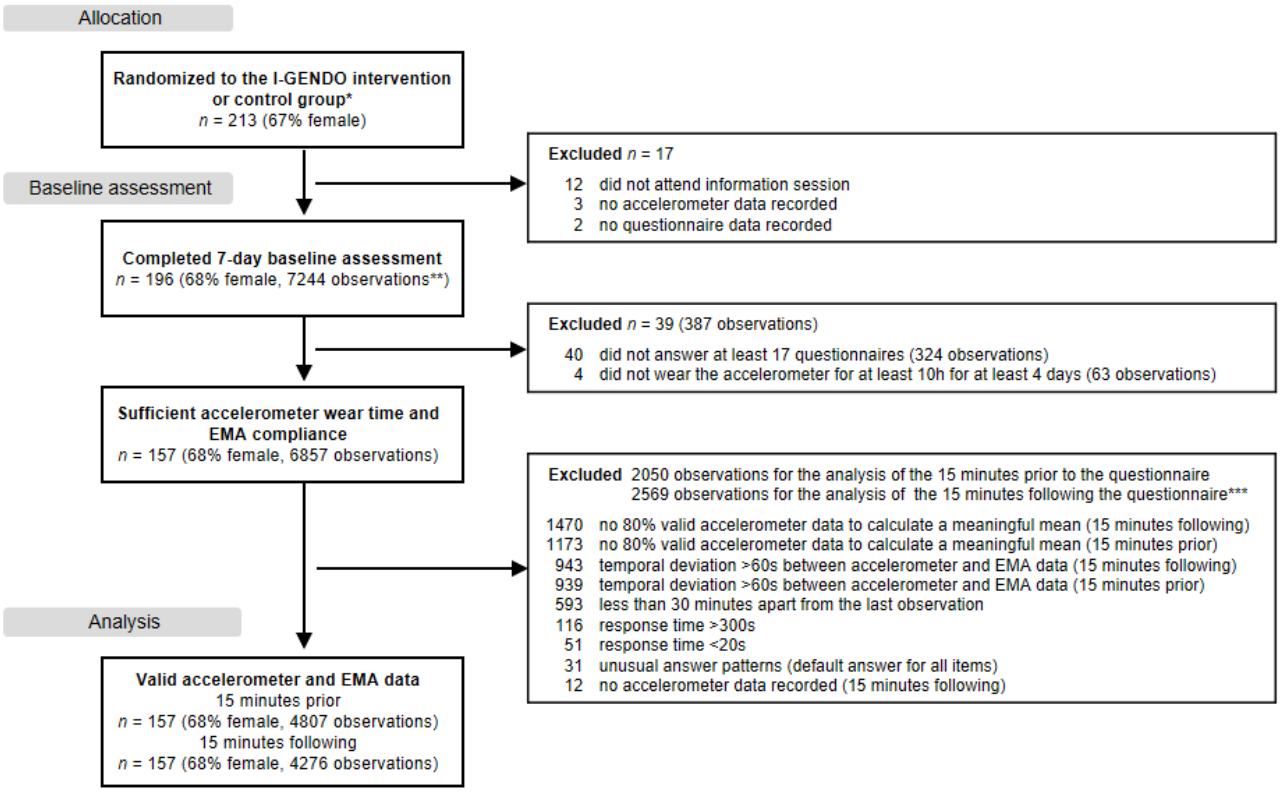
The ActiGraph® wGT3X-BT accelerometer were small-scale (4.6cm x 3.3cm x 1.5 cm), light weight (19 grams), and attached to an elastic waist belt.

Raw data was sampled at an input frequency of 30 Hz and initially stored on the device. Raw accelerations were filtered using the 'Normal Filter' mode and accumulated into 60-second epochs. Data was screened for non-wear periods using the waist-worn inclinometer algorithm[1] from ActiGraph® which classifies participant's posture into standing, sitting, lying, and non-wear/off. We excluded 60-second epochs with more than 30 'off' seconds (non-valid epoch).

[1] [1] https://docs.google.com/document/d/1EBAEcAL34k0ONZOgfXZPsMJJC-Uy9d49FFyPnmPH3Qc/edit?hl=en&authkey=CM--zvgE&pli=1#

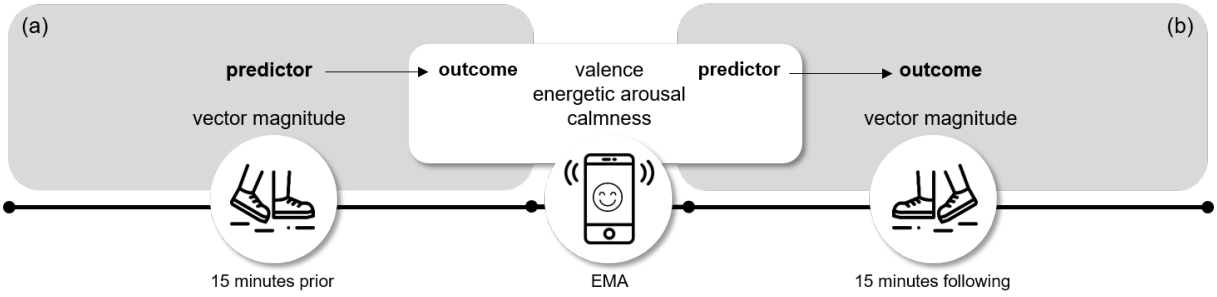
- **Figure S1.** Flow Chart of the data preparation process.

Participants with less than 10 hours of accelerometer wear-time for three or more days (non-valid days) were excluded. We further removed participants that completed less than 17 (30%) of the 56 EMA questionnaires (non-compliant) (Reichert et al., 2016).



*Participants were not informed of group assignment until after the 7-day assessment was terminated.
**An observation is defined as a measurement time point for which both questionnaire data and accelerometer data are available.
***Total number of excluded observations. Exclusion criteria can overlap.

- **Figure S2.** Illustration of the predicted association between physical activity and core affect



Legend. *Association between physical activity (PA) and affect (a) 15 minutes prior to and (b) 15 minutes following the ecological momentary assessment (EMA). PA (i.e., vector magnitude) was assessed continuously with an accelerometer. Core affect (i.e., valence, energetic arousal, calmness) was assessed via a questionnaire on participants smartphone at random occasions eight times a day. The time needed to complete the questionnaire was not considered in the analysis.*

- **Table S2.** R packages used for all analysis.

Package	Application	Reference
ggplot2 (v 3.3.5)	to generate visualizations	Wickham, H., Chang, W., & Wickham, M. H. (2016). Package 'ggplot2'. *Create elegant data visualisations using the grammar of graphics*. Version, 2(1), 1-189.
nlme (v. 3.1 – 155)	to fit multilevel models	Pinheiro, J., Bates, D., DebRoy, S., Sarkar, D., Heisterkamp, S., Van Willigen, B., & Maintainer, R. (2017). Package 'nlme'. *Linear and nonlinear mixed effects models,* version, 3(1), 274.
Performance (c. 0.8.0)	to check model assumptions	Lüdecke, D., Ben-Shachar, M. S., Patil, I., Waggoner, P., & Makowski, D. (2021). performance: An R package for assessment, comparison and testing of statistical models. *Journal of Open Source Software*, 6(60).
robustlmm	to fit robust models	Koller, M. (2016). robustlmm: an R package for robust estimation of linear mixed-effects models. *Journal of statistical software*, 75, 1-24.
sjPlot (v 2.8.10)	to generate tables of regression analysis	Lüdecke, D., & Lüdecke, M. D. (2015). Package 'sjPlot'. *R package version*, 1(9).

- **Statistical analysis.** Checking the assumptions

Assumptions were checked by visual inspection and if they appeared to be violated, a robust model was fitted and compared to the non-robust version. No noticeable difference emerged between both versions of the models. Model fit was not improved when controlling for autocorrelation.

Statistical analysis. Model fit A pre-registered hierarchical approach was used for the inclusion of the control variables and the model-fit was assessed with the Akaike information criterion. Maximum likelihood estimations were used to estimate model parameters and guide the inclusion of control variables. Models including all variables of interest based on theoretical considerations were run as a sensitivity analysis. These results did not differ from the hierarchical approach and were thus not reported. For the results see https://osf.io/p6xuf/?view_only=2e3db5614dcf4d1baaed797b359839c5

- **Statistical analysis.** Multilevel models

All continuous predictors (PA in the 15 minutes prior, valence, calmness, energetic arousal), were centred at the person-mean (Hoffman and Stawski, 2009) and included into the respective models at level 1 as fixed effects. Random effects for each predictor were included in the model. Non-significant random effects were excluded, resulting in different models for the predictors. Next, we entered a series of variables at level 1 as fixed effects to control for timely and diurnal variations: weekday or weekend (weekday=0, weekend=1), time-of-day (morning=00:00:00–11:59:59 (reference), afternoon=12:00:00–16:59:59, evening=17:00:00–23:59:59) and day in the study (0–6). PA in the 15 minutes prior to the prompt was added as an additional control variable at level 1 for the PA model. The person-mean of the respective predictor and sex (female=0, male=1), BMI (kg/m2) and age in years (both centred at grand-mean) were added at level 2 into the models (Additional File 1). Variables were only included in the final models if they improved the model-fit. Level for significance was set a priori to $\alpha<0.05$.

- **Figure S3.** Equations of the final models for the dependent variables (a) valence, calmness, energetic arousal and (b) VM in the 15 minutes following the prompt

(a)

Level 1 equation:

$$Y_{ij} = \beta_{0j} + \beta_{1j} * (VM\ 15\,\text{min}\,prior)_{ij} + \beta_{2j} * (wewd)_{ij} + \beta_{3j} * (afternoon)_{ij} + \beta_{4j} * (evening)_{ij} + r_{ij}$$

Level 2 equation:

$$\beta_{0j} = \gamma_{00} + \gamma_{01} * (mean\ VM\ 15\,\text{min}\,prior)_j + \gamma_{02} * (sex)_j + \gamma_{03} * (age)_j + u_{0j}$$

$$\beta_{1j} = \gamma_{10} + u_{1j}$$

$$\beta_{2j} = \gamma_{20}$$

$$\beta_{3j} = \gamma_{30}$$

$$\beta_{4j} = \gamma_{40}$$

(b)

Level 1 equation:

$$Y_{ij} = \beta_{0j} + \beta_{1j} * (valence)_{ij} + \beta_{2j} * (calmness)_{ij} + \beta_{3j} * (energetic\ arousal)_{ij} + \beta_{4j} * (VM\ 15\,\text{min}\,prior)_{ij} + r_{ij}$$

Level 2 equation:

$$\beta_{0j} = \gamma_{00} + \gamma_{01} * (mean\ valence)_j + \gamma_{02} * (mean\ calmness)_j + \gamma_{02} * (mean\ energetic\ arousal)_j + \gamma_{02} * (BMI)_j + u_{0j}$$

$$\beta_{1j} = \gamma_{10} + u_{1j}$$

$$\beta_{2j} = \gamma_{20}$$

$$\beta_{3j} = \gamma_{30}$$

$$\beta_{4j} = \gamma_{40} + u_{4j}$$

Additional File 2

- **Data preprocessing**

Ninty-three of the initial 196 participants were excluded from the analysis because they did not wear the sensor for at least 10h/day for at least four days (n = 4; 63 observations) or answered less than 17 EMA prompts (n = 35; 324 observations). The remaining 157 participants answered 6857 (M = 43.67, SD = 15.88, range: 17 – 98) EMA prompts while 8792 were planned to be delivered. Further, 2050 (15 min prior) and 2569 (15 min following) observations were excluded due to practical and statistical reasons, yielding a final observation count of 4807 (15 min prior) and 4276 (15 min following).

- **Attrition rate over the course of the 7-day assessment**

On the final day of the assessments (day 7) participants completed 15% fewer EMA prompts compared to the first day of the assessment (day 1: 1056, day 7: 896).

- **Between-person results**

Intraclass correlation coefficients (ICCs) of the null models indicated that 31% (valence), 33% (calmness), 25% (energetic arousal) and 7% (VM) were due to between-person differences.

AFFECT FOLLOWING PHYSICAL ACTIVITY

The day of the week (week day, weekend) showed a significant effect on the ratings of affect. This results means that on a Saturday or Sunday participants rating of valence and calmness increased by 3.66 and 4.99 respectively. In addition, the rating of all three subscales of affect was significantly higher for male than for female participants (valence: β=0.11, p=0.02, energetic arousal: β=0.17, p<0.001, calmness: β=0.10, p=0.04) and significant age differences were found for valence and energetic arousal. Being one year older than the group average was associated with higher values (valence: β=0.10, p=0.028, energetic arousal: β=0.11, p=0.007). Time of the day showed a significant effect insofar as the subjective rating of affect decreased (energetic arousal) and increased (calmness) throughout the day. ICCs showed that 68/68/65% of the variance in the model was due to within-person and 32/32/35% due to between-person variance for valence/energetic arousal/calmness respectively.

PHYSICAL ACTIVITY FOLLOWING AFFECT

Between-person results of the predictors indicate no significant effect. However, results for the control variables showed that individuals with a higher BMI recorded significantly lower VM in the 15 minutes following the assessment. This results means that a person with a BMI value that is one point higher than the group average, recorded 11.03 less VM in the following 15 minutes (β=-0.06, p=0.027). In addition, the recorded VM of a person was significantly higher when the VM in the 15 minutes prior to the assessment was increased (β=0.26, p<0.001). ICCs showed that 86% of the variance in the model was due to within-person and 14% due to between-person variance.

Chapter 3 | Study 2: A Tailored Gender-Sensitive mHealth Weight Loss Intervention (I-GENDO): Development and Process Evaluation

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The following article was first published in *JMIR Formative Research*

Pape, M., Färber, T., **Seiferth, C.,** Roth, T., Schroeder, S., Wolstein, J., Herpertz, S., Steins-Loeber, S. (2022). A Tailored Gender-Sensitive mHealth Weight Loss Intervention (I-GENDO): Development and Process Evaluation. *JMIR Formative Research*, 6(10), e38480. DOI: https://formative.jmir.org/2022/10/e38480/

Original Paper

A Tailored Gender-Sensitive mHealth Weight Loss Intervention (I-GENDO): Development and Process Evaluation

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Abstract

Background: Given the increase in the prevalence of overweight and obesity worldwide, the number of digital weight loss interventions has also risen. However, these interventions often lack theoretical background and data on long-term effectiveness. The consideration of individual and gender differences in weight-related psychological parameters might enhance the efficacy and sustainability of mobile-based weight loss interventions.

Objective: This paper presented an introduction to and the process evaluation of a 12-week gender-sensitive mobile health (mHealth) weight loss intervention (I-GENDO) combining computer-based and self-tailoring features.

Methods: Between August 2020 and August 2021, individuals with overweight (BMI 25.0-29.9 kg/m²), those with obesity class I (BMI 30.0-34.9 kg/m²), and those with obesity class II (BMI 35.0-39.9 kg/m²) were recruited to the I-GENDO project, a multicenter study in Germany. The mHealth intervention aimed at targeting individual psychological factors associated with the development and persistence of overweight and obesity (eg, emotional eating) using computer-based tailoring. Moreover, the intervention took a gender-sensitive approach by implementing self-tailoring of gender-targeted module versions. The computer-based assignment of the main modules, self-selection of gender-targeted module versions, and use patterns were evaluated while considering gender. Moreover, gender differences in the usability assessment were analyzed.

Results: Data from the intervention arm of the study were processed. A total of 116 individuals with overweight and obesity (77/116, 66.4% women; age mean 47.28, SD 11.66 years; BMI mean 33.58, SD 3.79 kg/m^2) were included in the analyses. Overall, the compliance (90/109, 82.6%) and satisfaction with the app (mean 86% approval) were high and comparable with those of other mobile weight loss interventions. The usability of the intervention was rated with 71% (5.0/7.0 points) satisfaction. More women obtained the main module that focused on emotion regulation skills. Most men and women selected women-targeted versions of the main modules. Women used the app more frequently and longer than men. However, women and men did not differ in the progress of use patterns throughout the intervention.

Conclusions: We developed a tailored gender-sensitive mHealth weight loss intervention. The usability of and engagement with the intervention were satisfactory, and the overall satisfaction with the intervention was also high. Gender differences must be considered in the evaluation of the effectiveness and sustainability of the intervention.

(JMIR Form Res 2022;6(10):e38480) doi: 10.2196/38480

KEYWORDS

mobile health; mHealth; eHealth; tailoring; gender; weight loss intervention; mobile phone

Introduction

Within the last few decades, a vast number of digital health apps have been developed worldwide [1,2]. eHealth interventions (ie, mobile health [mHealth] interventions) are cost-effective and feasible in everyday life and represent a useful addition to analog health care services, not only in times of a worldwide pandemic [3]. In 2021, 87% of German adults and adolescents aged >14 years owned a smartphone, and 27% reported using mHealth interventions regularly [4]. The use of mHealth interventions requires an active and self-determined engagement of the user and therefore facilitates behavioral changes [5]. For example, mHealth lifestyle interventions show good efficacy in promoting healthy behaviors such as dietary intake and physical activity [6-10]. Therefore, they are promising tools that could promote behavioral change in participants wishing to reduce weight [11]. However, most available interventions to date demonstrate only short-term effects of behavioral change, whereas long-term effectiveness, especially regarding weight loss, has either not been investigated or not been demonstrated [12-14]. An explanation for the lack of effects is that most weight loss apps have not been developed from a scientific background and thus lack sufficient consideration of psychological evidence-based strategies [15], which are an important aspect of effective weight loss programs (WLPs) according to international guidelines [16,17]. Moreover, most weight loss apps have been developed on a *one-size-fits-all* approach, despite indications from prior studies that targeted (tailored) interventions are more effective [18-20].

The term "tailoring" refers to the customization of a feature of an intervention based on the individual characteristics of the participants [21]. The participants might customize an intervention based on their own preferences (self-tailoring), or they might receive individualized interventions in which the program tailors the content, usually based on algorithms (computer-based tailoring). In the latter case, tailoring can be based on data from 1 assessment (static tailoring) or adapted to different assessments within an intervention process (dynamic tailoring). Studies have indicated that participants feel more strongly addressed by individualized interventions, are more satisfied with them, and are subsequently more engaged in their use, which enhances the efficacy of the programs [6,11,19,22-25]. Various psychological aspects are involved in the development and maintenance of overweight and obesity, including the experience of weight-related stigmatization [26], maladaptive coping strategies [27], or dysfunctional eating behaviors [28]. Therefore, developing computer-based tailoring features that consider such psychological aspects might be a key element in the optimization of digital WLPs.

Gender differences in the development and treatment of obesity and overweight have also been investigated [29,30]. In Germany, more men (43.3%) develop overweight (BMI 25-29.9 kg/m²) compared with women (28.8%), but there are no gender differences in the prevalence of obesity (BMI >30.0 kg/m²), with increasing prevalence rates in the past decades among both genders [31,32]. Men with overweight and obesity are less likely to accurately perceive their weight and are less dissatisfied with their overweight status [29]. Moreover, gender differences in physical activity, eating behavior, and weight-related psychological parameters have been reported. For example, women engage more often in problematic eating behaviors, such as emotional eating (EE) and craving of special foods than do men [33]. Women consistently report higher levels of perceived stress and engage more in emotion-focused coping, such as rumination, whereas men often use problem-focused or avoidant coping strategies [34,35]. On average, men are more physically active [36]. Some biological sex differences have been published; for instance, in males, fat depositions are often in the visceral depot, which increases their risk for cardiovascular disorders [37-39]. More women participate in WLPs, yet the participating men lose more absolute weight [40,41]. Results on the adherence to WLPs are heterogeneous, depending on the intervention type, among other factors [42-44]. On the basis of reviewed studies, investigating the effect of gender on overweight and obesity outcomes to improve the effectiveness of WLPs is an important research agenda. A recently published meta-analysis comparing the effects of gender-targeted and gender-neutral WLPs however revealed no differences in weight-related outcomes, although gender-targeted interventions were more effective in promoting activity and improving nutrition [45]. However, the included *gender-targeted* WLPs were offered either to male or to female participants based on sex. We support the idea that psychological interventions should be gender sensitive instead of gender dichotomous and assume an increase in the effectiveness of the intervention if it is gender sensitive [46]. Therefore, to avoid prejudiced gender-based distinctions between individuals with overweight and obesity, we recommend implementing gender-sensitive self-tailoring features.

Against this background, we aimed at developing a smartphone-based psychological and gender sensitive weight-loss intervention with computer-based and self-tailoring features. In the first part of this paper, we have described the development process of the app with particular focus on the tailoring features of the intervention. The subsequent process evaluation focuses on the evaluation of the app with regard to the psychological and gender-sensitive tailoring features, use patterns, and satisfaction with the app derived from a sample of 116 participants taking part in the I-GENDO project [47].

Methods

The I-GENDO Project

The project "Gender-sensitive enhancement of common weight-loss strategies for overweight and obesity: A personalized smartphone app" was proposed by the University of Bamberg, Departments of Clinical Psychology and Psychotherapy and Pathopsychology, in cooperation with LWL-University Hospital of Ruhr-University Bochum, Department of Psychosomatic Medicine and Psychotherapy, and funded by the Federal Ministry of Education and Research of Germany (01GL1719A/B). The project was preregistered (ClinicalTrials.gov identifier: NCT04080193).

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki. The Institutional Review Board of Ruhr-University

Bochum approved the study (number 18-6415). All participants were informed about the study and provided written informed consent.

Development of the mHealth Intervention I-GENDO

From September 2017 to November 2019, a modular app system was developed at the University of Bamberg in cooperation with an external software provider (groupXS Solutions GmbH).

Figure 1. The I-GENDO app interface.

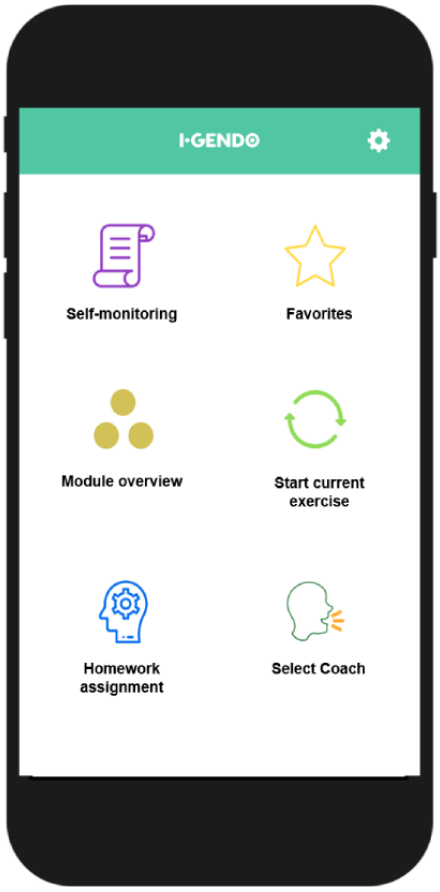


Figure 1 provides an overview of the I-GENDO app interface. The app provided the following elements: module-based psychological intervention; selection of an accompanying coach; and self-monitoring of hunger, appetite, and mood.

The content of the modules was based on the existing evidence-based manuals, qualitative data from focus groups of individuals with overweight and obesity, and interviews with experts in the field of psychological treatment of obesity. To implement a gender-sensitive approach, extensive literature reviews were conducted on the disparities between genders in the psychological and behavioral aspects of obesity treatment. Furthermore, a steering committee consisting of experts in the field of prevention and treatment of overweight and obesity, digital transformation, and qualitative data analyses was formed. All principal decisions regarding app development were made in consensus with the members of the steering committee.

On the basis of this information, 7 modules that served as the heart of the 12-week I-GENDO intervention were constructed. Of the 7 modules, 2 modules addressed the introduction to (goal setting) and conclusion (relapse prevention strategies) of the intervention. The remaining 5 modules (main modules) focused on different psychological parameters associated with the development and maintenance of overweight and obesity: stress management skills (*stress module*), emotion regulation skills (*emotion module*), dealing with the consequences of overweight (*consequences module*), self-regulation skills (*control module*), and self-efficacy (*self-efficacy module*). Each module contained 9 sessions, which included psychoeducational elements delivered through texts and videos, several therapeutic tools from different therapeutic approaches (ie, cognitive behavioral therapy, dialectical behavioral therapy, and mindfulness), and various behavior change techniques [48]. These sessions could be repeated as many times as desired, and users could set a short link to their favorite exercises via the toolbox.

Each module was presented in either a women-targeted version (*version A*) or a men-targeted version (*version B*), which differed in terms of knowledge transfer, communication style, and prioritization of topics. For example, in the *stress module*, this was achieved using appealing case examples in the women-targeted version and fact presenting in the men-targeted version to transfer general knowledge about stress. Another example is that the men-targeted version in the *emotion module* highlighted and trained the recognition and labeling of emotions, whereas in the women-targeted version, the association between

dysfunctional beliefs and eating behavior was prioritized. Multimedia Appendix 1 [48-77] provides an overview of the operationalization of the gender-sensitive modules and the origin of evidence. The versions were briefly introduced, with both introductions presented on 1 screen page. Participants could then freely choose between *version A* or *B* regardless of biological sex (gender-sensitive instead of gender dichotomous tailoring). Participants were blind to the manipulation of the gender-targeted versions.

Process Evaluation of the mHealth Intervention I-GENDO

From December 2019 to December 2021, the effectiveness of the 12-week I-GENDO intervention was evaluated in a randomized controlled trial conducted at the University of Bamberg and LWL-University Hospital Bochum, Department of Psychosomatic Medicine and Psychotherapy (ClinicalTrials.gov Identifier: NCT04080193). The main results of the randomized controlled trial will be published elsewhere. In this manuscript, the relevant process evaluation data from the intervention arm were analyzed.

Study Sample

Individuals were informed about the I-GENDO project via newspaper articles, radio features, and oral presentations at rehabilitation centers. Participants interested in the study were screened for eligibility (Textbox 1) and, if eligible, were invited to participate. According to the guidelines of the German Association for the Study of Obesity and the German Society for General and Visceral Surgery, individuals with obesity class III (BMI >39.9 kg/m^2) experience a complex multifactorial framework of severe social, mental, and physical problems and are recommended to undergo bariatric surgery. Therefore, we excluded individuals with obesity class III from participation but provided further support. Because the effect of bariatric surgery on weight loss is mainly driven by physical limitations and varies significantly between the types of operative procedure [78], we decided to exclude individuals who underwent or planned to undergo bariatric surgery. The total study sample consisted of 213 individuals with overweight and obesity, of which 116 (n=77, 66.4% women) were randomly assigned to the intervention group for this study and subsequently included in this analysis.

Textbox 1. Eligibility criteria of the I-GENDO project.

Inclusion criteria

- Legal age (≥18 years)
- Obesity class I or II with subjectively experienced weight-related impairment and a current intention to lose weight
- Overweight (ie, BMI between 25 and 29.9 kg/m²) with weight-related health problems, visceral adipose tissue, or high psychosocial weight-related distress and a current intention to lose weight

Exclusion criteria

- Obesity class III (ie, BMI >39.9 kg/m²)
- Current (or within the last 12 months) involvement in a structured weight loss intervention
- Insulin-dependent type 1 diabetes
- Previous or intended bariatric surgery
- Current psychotherapeutic treatment of weight-related health problems
- Weight-enhancing drugs
- Drugs that promote weight loss (eg, antiobesity drugs)
- Weight-enhancing health problems that are not yet treated
- Cancerous disease within the last 5 years
- Current substance-use disorders, major depression, psychosis, suicidal tendency, or pregnancy
- Severe cognitive impairments
- Insufficient knowledge of the German language
- Binge-eating disorder or bulimia nervosa

Intervention Phase

Participants in the intervention group received a 12-week tailored app intervention. In the first week of intervention, the introduction module was unlocked for each participant, followed by 9 weeks of tailored intervention comprising 3 of the 5 main modules. Each session of the 3 main modules was unlocked successively between weeks 2 and 9. The basic, minimal content of the remaining 2 modules was provided in the form of mini modules, which were unlocked in week 11. Finally, the conclusion module was provided to each participant in week 12.

Tailoring

Figure 2 displays computer-based and self-tailoring features of the intervention. The introduction and conclusion module were mandatory elements framing the intervention that conveyed general content, whereas the main modules targeted individual

differences in weight-related psychological parameters. The main module assignment was computer-based and depended on the results of the Revised Illness Perception Questionnaire (IPQ-R), a standardized questionnaire adapted to overweight and obesity that measures illness beliefs (eg, "my overweight strongly affects the way others see me") and causal attribution of overweight (eg, "my emotional state, e.g. feeling down, lonely, anxious, empty") [79]. Participants completed the IPQ-R at the baseline assessment. Each of the 32 items were rated on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). In this study, the internal consistency of the scale was good (Cronbach α=.714). Scales were regenerated with higher means representing severe problems on the related psychological parameters associated with overweight and obesity (eg, EE). Of the 5 dimensions, 3 on which the participants reported the highest impairments were tailored to the participants (computer-based tailoring). In addition to the computer-based tailoring feature, individual adaption of content and functions was enabled (self-tailoring). Each module was presented in either a men-specific (*version B*) or a women-specific version (*version A*; "App features" section and Multimedia Appendix 1). The app additionally contained customization features to enhance the adherence to the intervention [80]. In particular, the participants could choose between different coaches at the beginning of the 12-week intervention. A total of 4 different coaches were introduced: 2 men and 2 women coaches depicted as being either more friendly (eg, informal and motivating tips) or more professional (eg, formal and directive tips).

Figure 2. Tailoring features of the I-GENDO intervention. Of the 5 main modules (in the box), 3 were assigned to the participants based on the results of the revised illness perception questionnaire (computer-based tailoring). Each of the modules was presented in either a women- or men-targeted version (self-tailoring).

Measurements

Engagement With the App

Use patterns were retrieved from individual app data and subsequently analyzed. Actions were defined as time slots of active engagement with the app, for example, log-in to the app and processing a session (use frequency). Inactivity for 20 minutes defined the completion of one action. The overall app use time was calculated in minutes (use time). The participants who used the app at least 12 times (actions) and for 120 minutes within the 12-week intervention were defined as being compliant with the I-GENDO app.

Satisfaction With the App

At the end of the conclusion module, the users could give feedback about their satisfaction with the app and the relevance and daily usefulness of the app on scales ranging from 0 ("not at all") to 100 ("very much"). In the last session of each module, participants could evaluate how satisfied they were with the corresponding module.

Usability Rating of the App

After the 12-week intervention, the mHealth App Usability Questionnaire for stand-alone mHealth apps used by patients was administered [81]. The original English questionnaire was translated into German by a member of the research group and retranslated by a native speaker. Deviations were discussed and subsequently adjusted. The self-report questionnaire consisted of 18 items, which were scored on a scale from 1 ("strongly disagree") to 7 ("strongly agree"), with higher means reflecting higher usability. Prior research indicated good psychometric properties of the English version of the mHealth App Usability Questionnaire [81]. In this study, the internal consistency of the total scale was excellent (Cronbach α=.935).

Data Analysis

All analyses were conducted using SPSS for Windows (version 26.0; IBM Corp) and Excel (version 16.0; Microsoft Corp). App data were retrieved from Apache CouchDBTM. Descriptive analyses were conducted using percentages and frequencies for categorical variables and means and SDs for continuous variables. *Chi-square* distributions that compared categorical variables between genders were implemented, and Bonferroni-adjusted independent 2-tailed *t* tests were conducted to compare metrically scaled variables. Mann-Whitney *U* tests were conducted to compare results between genders on nonnormally-distributed variables. Friedman tests and Dunn-Bonferroni post hoc tests were implemented to compare app engagement between genders over the 12 weeks of intervention.

Results

Participants

We found no significant gender differences in age, BMI, marital status, and education level at baseline (Table 1).

Table 1. Sociodemographic factors (N=116).

Characteristic	Overall	Women (n=77)	Men (n=39)	Women vs men		
				2-tailed t test (*df*)	Chi-square (*df*)	*P* value[a]
Age (years), mean (SD)	47.28 (11.66)	46.40 (12.22)	49.00 (10.38)	1.14 (114)	N/A[b]	.26
BMI (kg/m^2), mean (SD)	33.58 (3.79)	33.75 (3.69)	33.23 (4.02)	0.70 (114)	N/A	.49
Marital status (yes), n (%)[c]	91 (78.4)	57 (74)	34 (87)	N/A	1.9 (1)	.17
Education (university), n (%)[d]	36 (31)	25 (32)	11 (28)	N/A	0.1 (1)	.80

[a]Bonferroni-adjusted *P* values.

[b]N/A: not applicable.

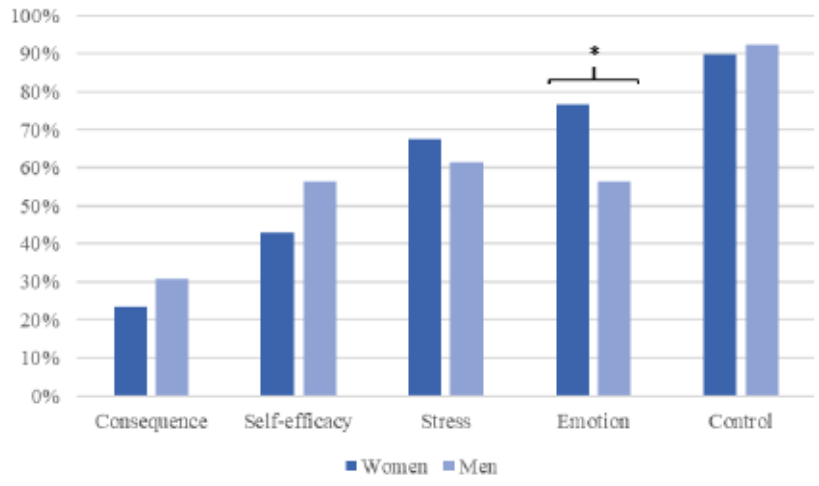
[c]Number of participants in a relationship.

[d]Number of participants with a university degree.

Tailoring

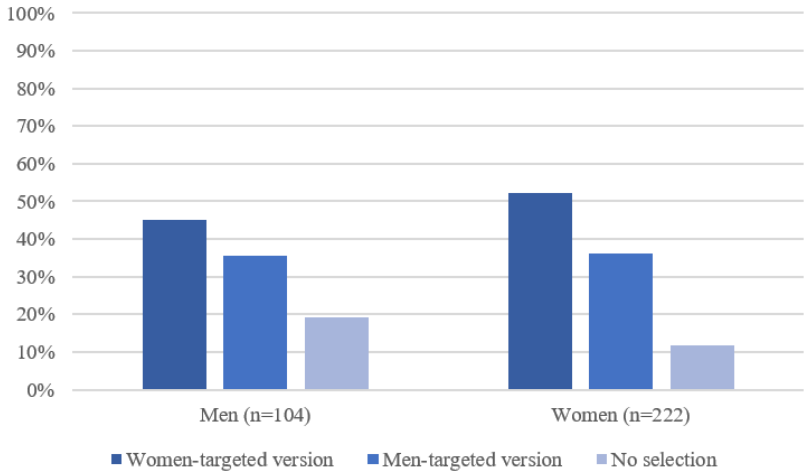
Three main modules were tailored to each of the 116 participants by computer-based tailoring according to their IPQ-R results (see the section *Tailoring*). Most participants (105/116, 90.5%) received the *control module*, followed by the *emotion module* (81/116, 69.8%), *stress module* (76/116, 65.5%), and *self-efficacy module* (55/116, 47.4%). One-quarter of the participants (30/116, 25.9%) received the *consequence module*. Figure 3 illustrates the module assignments for the participating men and women separately. Significantly more women obtained the *emotion module* than men (χ^2_1=4.1; *P*=.04; ϕ=0.21). The genders did not differ in the assignment of the *consequence* (χ^2_1=0.4; *P*=.53), *self-efficacy* (χ^2_1=1.6; *P*=.23), *stress* (χ^2_1=0.2; *P*=.66), or *control module* (χ^2_1=0.02; *P*=.89).

Figure 3. Assigned full-version modules (computer-based tailoring) in percentage (*P<.005).



As described earlier, at the beginning of each module, the participants were instructed to choose between either a women-targeted or a men-targeted version (self-tailoring). In 50% (163/326) of the choices, the women-targeted versions were selected (women: 116/222, 52.3%; men: 47/104, 45.2%). In 35.9% (117/326) of the choices, the men-targeted versions were selected (women: 80/222, 36%; men: 37/104, 35.6%). In the remaining 14.1% (46/326) of the choices, no selection was made (Figure 4). When the participants did choose a version, they chose version A 58.2% (163/280) of the time (women: 116/196, 59.2%; men: 47/84, 56%).

Figure 4. Module version assignments (self-tailoring) in percentage (total choices: N=326).



Another customization feature of the intervention was the selection of an accompanying coach when starting the app for the first time. Most women (35/74, 47%) chose a friendly woman coach, 19% (14/74) chose a professional man coach, 18% (13/74) chose a friendly man coach, and 16% (12/74) chose a professional woman coach. Coach assessment in men was more balanced, with 34% (12/35) choosing a friendly woman coach, 23% (8/35) choosing a friendly man or professional woman coach, and 20% (7/35) choosing a professional man coach. No significant gender differences were found in coach assessment (χ^2_3=1.9; *P*=.60).

Engagement With the App

Of the 116 participants in the intervention group, 109 actively participated in the app intervention phase. During the 12-week intervention period, the use frequency and use time were recorded.

We found significant gender difference in use frequency (*U*=908.00; *z* score=−2.51; *P*=.01; *r*=−0.24) and use time (*U*=736.00; *z* score=−3.63; *P*<.001; *r*=−0.35). The participating women used the app 97 (SD 88.03) times and for 625 (SD 427.94) minutes on average throughout the intervention, whereas the participating men used the app 56 (SD 45.62) times and for 347 (SD 285.68) minutes on average. In total, 82.6% (90/109) of the users were compliant with the app (women: 63/74, 85%; men: 27/35, 77%).

During the 12-week intervention phase, the use time (χ^2_{11}=126.03; *P*<.001) and use frequency (χ^2_{11}=139.51; *P*<.001) of the participating men (n=35) decreased (Figures 5 and 6). The use time, (χ^2_{11}=231.34; *P*<.001) and use frequency (χ^2_{11}=309.16; *P*<.001) of the participating women (n=74) also decreased. Dunn-Bonferroni post hoc tests revealed a significant decrease in use time within the first 3 weeks of intervention (*z* score=3.99; *P*<.001; *r*=0.46). From week 3 to week 12, use time and frequency leveled off at approximately 6.56 (SD 7.21) actions per week and 41.99 (SD 34.03) minutes per week for the participating women and 3.53 actions per week (SD 3.36) and 21.75 minutes per week (SD 21.88) for the participating men. We found no gender differences in use time progress (*U*=1075.00; *z* score=−1.43; *P*=.15) and use frequency progress (*U*=1106.00, *z* score=−1.23; *P*=.22) during the 12-week intervention period.

Figure 5. Use time per week in minutes (means and SEs of means).

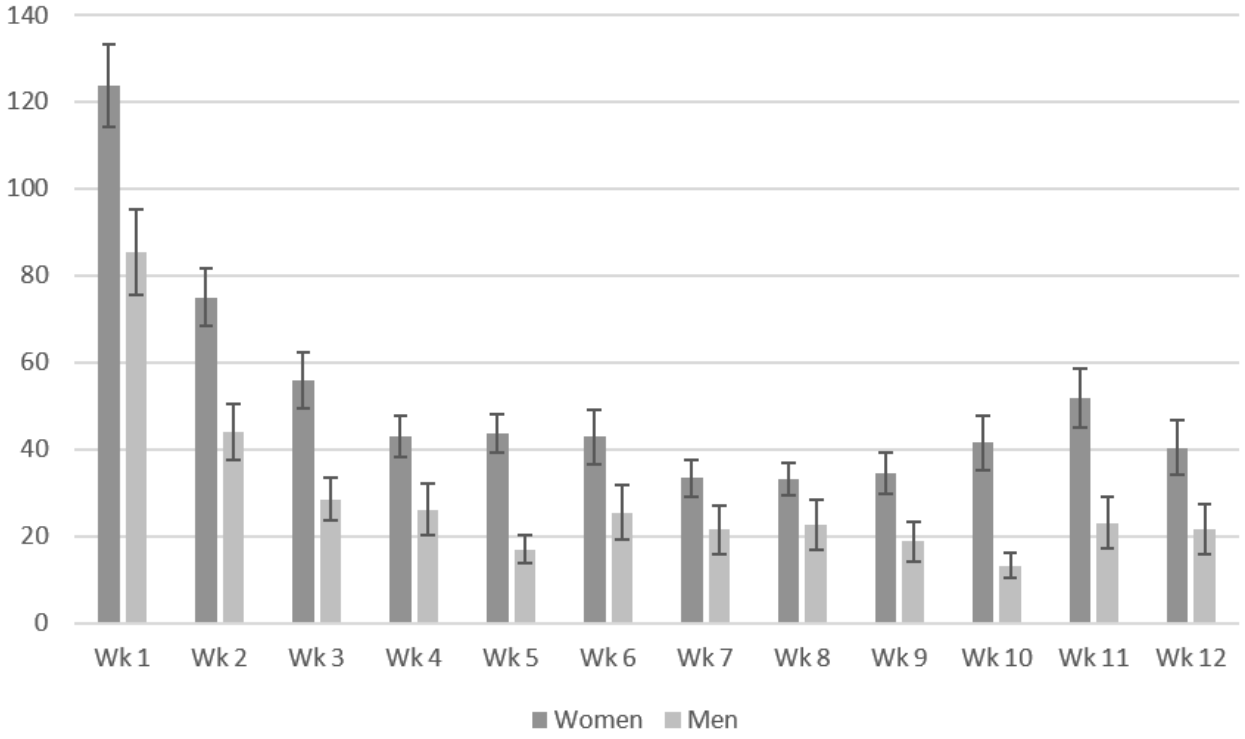
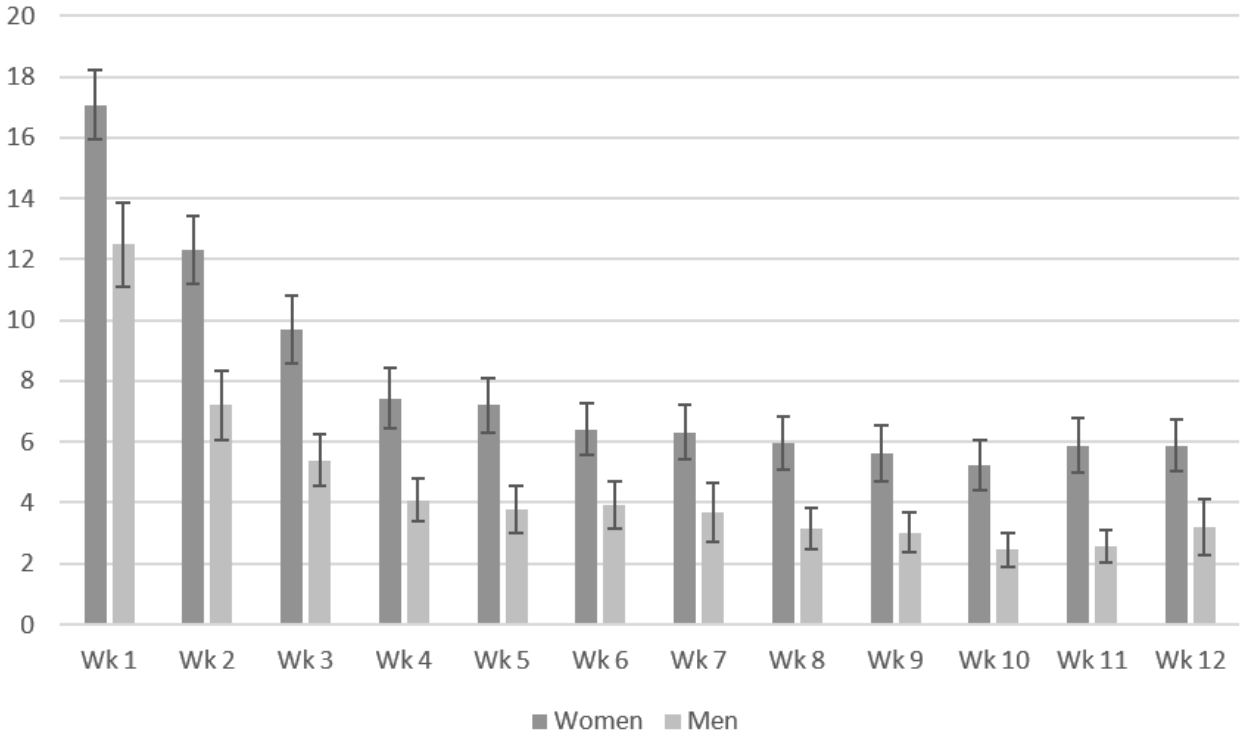


Figure 6. Use frequency per week in actions (means and SEs of means).



Evaluation of the App

After completion, 41 participants evaluated the I-GENDO app. On average, the overall satisfaction with the app was high (mean 85.54, SD 19.36). In addition, the relevance of the content (mean 83.34, SD 20.03) and daily life usefulness (mean 78.95, SD 22.24) were evaluated as satisfactory. Of the main modules, the *stress module* (n=36) was rated best (mean 82.92, SD 14.05), followed by the *emotion module* (n=50; mean 81.66, SD 16.45), the *control module* (n=60; mean 80.47, SD 18.08), the *self-efficacy module* (n=29; mean 78.48, SD 17.66), and finally the *consequence module* (n=16; mean 67.75, SD 21.68).

In addition to the evaluation, the usability of the app was assessed using a standardized questionnaire (see the section *Usability Rating of the App*). The usability of the app was rated, on average, with 71% satisfaction (mean 5.00, SD 1.08 points; maximum: 7.00 points). No gender differences could be found between the usability ratings of men (mean 4.72, SD 1.07) and women (mean 5.13, SD 1.07; t_{99}=−1.76; *P*=.08).

Discussion

Overview

We aimed to introduce the I-GENDO app, a tailored gender-sensitive mHealth weight loss intervention, and present results from its process evaluation data. Therefore, data from the intervention arm of the I-GENDO project were analyzed. The sample included 116 (n=77, 66.4% women) individuals with overweight and obesity.

Principal Findings

We developed a module-based 12-week intervention combining computer-based and self-tailoring features. Most participants (105/116, 90.5%) received the *control module*, which focused on self-regulation skills of food craving. The *stress module* was assigned to 65.5% (76/116) of the participants, and the *self-efficacy module* to 47.4% (55/116). The *consequence module* was obtained by 25.9% (30/116) of the participants. Significantly more women (59/77, 77%) than men (22/39, 56%) received the *emotion module*. Another tool of the intervention was the implementation of gender-sensitive self-tailoring features. We developed women- and men-targeted versions of the main modules. At the beginning of each module, participants could choose between the 2 versions. Among the participants who chose a version, *version A* was chosen 58.2% (163/280) of the time (women: 116/196, 59.2%; men: 47/84, 56%), which means that among both genders, the women-targeted module versions were predominantly selected.

In total, 82.6% (90/109) of the participants (women: 63/74, 85%; men: 27/35, 77%) were compliant with the I-GENDO app during the intervention phase. Use time and frequency significantly decreased during the 12-week intervention phase for both genders. After the first 3 weeks of intervention, use time leveled off and remained stable at approximately 42 minutes per week for the participating women and 22 minutes per week for the participating men. Similarly, use frequencies were approximately stable as of week 3 for both genders. Compared with the women, the men used the app infrequently and spent less time with the app. Nevertheless, the average use times and frequencies in both genders were satisfactory even in the last weeks.

The overall satisfaction with the app was high, with almost 86% (86/100) approval. In addition, the daily life usefulness and relevance of the content were ranked satisfactory by 79% (79/100) and 83% (83/100) of participants, respectively. The highest-rated main module was the *stress module* (83/100, 83%), but even the satisfaction with the *consequence module* was acceptable (68/100, 68%). In general, the usability ratings indicated that the I-GENDO intervention was good, averaging 5.0 out of 7.0 points (71%).

Comparison With Prior Work

The heterogeneous computer-based administration of the main modules supports the tailoring feature. The *control module* was assigned to most participants. This is in line with the observation that decreased food-related inhibitory control is regularly associated with overweight and obesity [49,82,83]. Gender differences were found in the computer-based assignments of the *emotion module*, which significantly more women obtained. The module focused on dysfunctional emotion regulation and associations between negative emotions and (eating) behavior. EE refers to problems in the distinction between physiological appetite and eating as a strategy to cope with negative feelings [84]. EE is correlated with higher weight, severe depression symptoms, and the consumption of sweet energy-dense foods [85]. More women report negative emotions as causes for their overweight and engage more often in EE compared with men [50,85,86]. EE is associated with less intuitive eating by women, which could be a barrier to the implementation of healthy eating behaviors [87]. Studies indicate that more women undergo weight loss treatment, whereas participating men lose more absolute weight [29]. Focusing more on EE in treatment might contribute to a close in this gap. In addition, previous studies indicated that a relevant subgroup of individuals with overweight and obesity exhibit addiction-like eating behavior (ie, food addiction [FA]), characterized by an impaired food-related inhibitory control, EE, and food craving [88,89]. The prevalence of FA is higher in women than in men and is among other factors associated with higher BMI, dysfunctional eating behavior, and psychological distress [90,91]. Some studies reported lower adherence to and decreased effectiveness of WLPs in individuals experiencing FA, whereas others found no influence of FA on the success of WLPs [92-95]. As the *control* and *emotion* modules implement the treatment of dysfunctional EE behavior and exercises to improve food-related inhibitory control, participants experiencing FA might especially benefit from the intervention. Thus, the association between FA and the effectiveness of our intervention should be further investigated.

One-quarter of the participants received the *consequences module*, which focused on weight-related discrimination and the improvement of self-esteem and body image, as well as the social competences to deal with discrimination. The extent of this use might explain the prevalence of weight discrimination being higher in our sample than in the results of a representative German study reporting prevalence rates ranging from 5.6% to 18.7% in individuals with overweight and obesity (classes I and II) [96]. We hypothesized that individuals who have experienced discrimination might prefer seeking WLPs based on psychological rather than lifestyle features. Moreover, in our study, the *consequence module* was assigned to more men (12/39, 31%) than women (18/77, 23%), which appears to be in contrast to the results of the previously cited study that reported double the prevalence of weight-based discrimination in women [96]. The anonymity of a smartphone-based intervention combined with the opportunity to receive specialized psychological support targeted to individual needs could have been particularly appealing for men who had experienced weight-related discrimination and were affected by the consequences of their overweight. Nevertheless, the

module generally focused on weight-related emotional and physical consequences, which might be appealing to individuals with overweight and obesity regardless of whether they experienced discrimination.

Gender differences in health care services are an important consideration for the improvement of treatment outcomes [97]. Prior studies have indicated gender differences in eating behavior, as well as the psychological factors associated with weight gain and maintenance, highlighting the need for gender-targeted weight loss interventions [29,40]. As the effectiveness of gender dichotomous tailoring does not significantly differ from that of gender-neutral interventions [45], we implemented gender-sensitive self-tailoring features. The participants could choose between 2 gender-targeted versions at the beginning of the modules. The selection of the versions was heterogeneous, with most participants choosing women-targeted versions. This result supports the idea of gender-sensitive interventions to overcome gender binary [46]. However, its influence on the effectiveness of the intervention needs to be further investigated.

In complex digital interventions, the consideration of relevant process evaluation data (eg, usability testing and use patterns) is crucial before interpreting the effectiveness of the intervention [98]. The compliance with the app was satisfactory (90/109, 82.6%) and comparable with other studies. Signal et al [99] developed an eHealth intervention for prediabetes and diabetes self-management. They reported that 74% of the participants were actively engaged (ie, any use data were detected at any time throughout the 16-week intervention). Ruf et al [100] developed an mHealth intervention that assesses event-contingent dietary intake and physical activity, as well as relevant psychological parameters. Compliance, defined as the percentage of complete prompts within the total number of prompts received, was 80%. Another mHealth intervention focused on the management of food-related impulses to facilitate weight loss [101]. In that study, the completion rate (the number of participants who provided data at the 3-month follow-up) was 76%. These findings suggest that our compliance rate is comparable or even higher, although the differences in operational definitions cloud the interpretation.

Throughout the intervention, the use time and frequency decreased in both genders. Decreases in engagement were also reported in other studies; that is, in those with extended intervention periods [99,102]. Reductions in engagement and high dropouts are typical for internet-based interventions and are caused by a variety of reasons [103]. We hypothesized that the reduction in engagement observed in our study might be associated with the high number of competing commercial digital weight loss interventions, which might be less demanding, compared with psychological interventions. Moreover, the intervention phase of our study fell within the first and second lockdowns of the COVID-19 pandemic in Germany in 2020. During this period, the level of psychological distress increased, and vulnerable people engaged more often in dysfunctional eating patterns (ie, EE) [104]. In addition, many people were affected by short-term work or job losses and subsequent income losses [105]. It is likely that people neglected the intervention during this burdensome period.

The results from previous studies on the adherence to mHealth interventions are heterogeneous, with some reporting higher engagement in men [29,40,106] and others reporting higher engagement in women [99]. In our study, women used the app more frequently and spent more time on it. In the general German population, women report higher smartphone use time (mean 167 min/day) than men (mean 154 min/day), which might at least partially explain these differences [107]. Moreover, women are more interested in body appearance and health-related topics than men and use the internet more frequently for medical and health research [108-110]. Studies have also reported that women are more likely to use mHealth interventions focusing on nutrition and self-care apps, whereas men are more likely to use fitness apps [111-113]. Therefore, the lower engagement of the participating men in this study might be because the app focused on psychological rather than physiological determinants of overweight and obesity.

As reported in a recently published systematic review [114], other studies on mHealth interventions have either failed to report gender differences in the adherence to and usability of these interventions or reported results from biased samples with approximately 90% of women [115-117]. Given that higher engagement in mHealth interventions is usually associated with better outcomes [22,24,118], we propose that the samples in future studies should be more balanced with regard to gender and implement gender-sensitive feasibility and usability testing. Overall, the compliance with the app (90/109, 82.6%) and satisfaction with the app (86/100, 86%) were high and comparable with those of other mHealth interventions [99-101,119]. The usability of the app was rated with 71% (5.0/7.0 points) satisfaction. Other evidence-based mHealth weight loss interventions reported comparable or even lower usability scores, between 61.9% and 69.3% [100,119]. In addition, Ferrara et al [120] reviewed the usability of commercial weight loss apps, which can be downloaded from Google Play and the Apple Store. Scientists ranked the usability of these apps between 47% and 89%.

Limitations

In our study, men and women differed in the assignment of main modules, which focused on psychological parameters associated with the development and maintenance of overweight and obesity. Interestingly, most men and women selected the women-targeted versions of the main modules. Given that the participants were blind to the gender-targeted manipulation, we suggest that the selections were not influenced by social desirability. Future studies should distinguish between gender differences based on the results from explicit and implicit assessments to adjust for social norms. Moreover, the participants were forced to select one version at the beginning of each module and were not allowed to switch versions. A reasonable approach could be to allow participants to test both versions to enhance their adherence to the app. In addition, it should be verified whether the introductions of the versions sufficiently hint at different module content.

It should be noted that only few participants (41/109, 37.6%) evaluated the app after completion. The evaluation was voluntary and was assessed at the end of the last session of the

intervention. Therefore, results regarding satisfaction with the app and the main modules should be interpreted cautiously.

The results from the process evaluation revealed that men and women differed in their app use. Women used the app more frequently and longer than men. Most of the scientists involved in the development process were women. Therefore, the women-targeted features of the app might have been more salient and thus confounded the selection by both genders. This methodological aspect might subsequently explain the higher use patterns of the participating women. Future studies or revisions of the app intervention should involve men scientists.

Conclusions

In summary, given the high diversity in module assignment, we hypothesize that tailoring was successfully implemented in the intervention. The heterogeneous selection of the gender-targeted features might underscore the need for gender-sensitive (self-tailoring and blind choice) instead of gender dichotomous (computer-based tailoring) targeting but could also hint at methodological limitations, which need to be considered and further investigated in future studies. Further studies need to clarify whether the reported gender differences in the use and evaluation of the app confound the effectiveness and sustainability of the I-GENDO intervention.

Acknowledgments

The Federal Ministry of Education and Research, Germany funded this study. The authors would like to acknowledge support from the Open Access Publication Funds of the Ruhr-Universität Bochum. The authors would also like to acknowledge Zoé Blumenwitz for research assistance.

Authors' Contributions

MP was involved in conceptualization, the acquisition of data, formal analysis, the interpretation of data, and the writing of the original draft. TF was involved in the acquisition and interpretation of data, review, and editing. CS and TR were involved in the acquisition of data, review, and editing. SS contributed to the study design. JW and SH contributed to the study design, supervision, review, and editing. SS-L contributed to the study design, conceptualization, study supervision, review, and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Evidence, content, and adaptions of the gender-sensitive main modules.
[DOCX File , 55 KB-Multimedia Appendix 1]

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Abbreviations

EE: emotional eating
FA: food addiction
IPQ-R: revised illness perception questionnaire
mHealth: mobile health
WLP: weight loss program

Edited by A Mavragani; submitted 05.04.22; peer-reviewed by H Meggy, H Ranjani; comments to author 11.07.22; revised version received 11.08.22; accepted 29.08.22; published 27.10.22

Please cite as:
Pape M, Färber T, Seiferth C, Roth T, Schroeder S, Wolstein J, Herpertz S, Steins-Loeber S
A Tailored Gender-Sensitive mHealth Weight Loss Intervention (I-GENDO): Development and Process Evaluation
JMIR Form Res 2022;6(10):e38480
URL: https://formative.jmir.org/2022/10/e38480
doi: 10.2196/38480
PMID:

Table S1. Evidence, content and adaptions of the gender-sensitive main modules

Evidence [origin]	Module	Module Content	Behavior Change Techniques[1]	Gender-Specific Adaptations
– Association between chronic stress (high levels of glucocorticoids) and unfavourable eating styles, negative affect and body weight [2] – Stress is a risk factor for obesity [3] – Women and men with obesity report more stressful live events than normal weight individuals [4] – Assumption that men with obesity tend to prefer individual, self-guided programs, which focus on facts rather than "feelings", prefer factual information on how to lose weight, men tend to	*Stress Module*	- psychoeducation: general information about stress development, responses and management - exercises to identify individual stress and stress responses and (dys)functional coping behavior - exercises to identify associations between stress and individual eating behavior, weight gain and well-being [8], [9] - exercises to improve personal stress management and coping skills based on the stress management training of Gerd Kaluza (i.e., time management, mindfulness, problem solving)[10], [11].	Self-monitoring of behavior Social support (emotional) Behavior substitution Behavioral rehearsal/practice Action planning Problem solving	**Version A:** - psychoeducation based on relatable case examples **Version B:** - psychoeducation based on relatable gender-specific statistics, facts and data

prefer technical information and becoming an expert of their condition [5]–[7]				
– Association between emotional eating and weight gain [12] – Women with obesity report a high burden by emotional states [focus groups]* – Gender differences in emotional competences, emotional eating, usage of emotion-regulation strategies , women tend to engage in rumination more often than men [13], [14] – Women tend to be more aware of their emotions and engage in more (mal)adaptive emotion regulation	*Emotion Module*	- psychoeducation: general information about emotions and development of emotions (emergence of emotions due to weight and weight discrimination) and associations to behavior - exercises to identify associations between emotions and (eating) behavior[15] - exercises to build functional emotion regulation skills based on the Dialectical behavior therapy (DBT)[9], [16]	Self-assessment of affective consequences Self-monitoring of behavior Behavior substitution Behavioral experiments Emotional consequences Regulate negative emotions	**Version A:** - associations between cognition and dysfunctional beliefs (ABC model) [17] - focusing on rumination as dysfunctional emotion regulation strategy **Version B:** - identifying, labelling emotions, building up basic emotional competences (DBT manual) [16] - focusing on suppression as a dysfunctional emotion regulation strategy

strategies than men [14]				
– Men and women with overweight and obesity experience weight discrimination in multiple areas of life, gender difference in consequences and coping behavior [18], [19] – Men with obesity experience weight-loss as a competition and a project against themselves, commitment to "masculine" hard work [focus groups]* [20] – Men reported more physical and women reported more emotional consequences of overweight [focus groups]*	*Consequences Module*	- psychoeducation: general information about weight-related consequences (e.g., weight discrimination) [9] - associations between weight discrimination and weight management - exercises to improve self-esteem and body image[8], [15] - exercises to improve social competences (self-confident behavior) based on social competence group trainings [21]	Emotional consequences Social and environmental consequences Self-monitoring of behavior Social support (general) Behavioral experiments	**Version A:** - highlighting the emotional consequences of (internalized) weight discrimination - CBT-based tools to improve body image and social competences [9], [21] **Version B:** - highlighting the physical consequences of overweight - offering competitive challenges and tasks to improve physical well-being and social competences
- Association between weight,	*Control Module*	- psychoeducation: general information about the	Behavior substitution Behavioral rehearsal/practice	**Version A:**

eating behavior and impulsivity [22], [23] - Men with obesity tend to prefer weight-loss programs which enable control and autonomy and promote problem-solving; loss of control is incoherent with male role [6], [7], [24] - Women with obesity reported higher levels of restraint eating, rigid avoidance of situations and food cues that trigger loss of control and a dichotomous thinking style [focus groups]* - Lack of long-term regulation strategies [focus groups]*		association between self-regulation and impulsivity and weight-related outcomes [8], [9], [15] - identify associations between loss of control eating and contextual or personal aspects - exercises to improve self-regulation in general and food-related inhibitory control in particular in individually meaningful critical situations [25]	Generalization of a target behavior Prompts/cues Self-monitoring of behavior Avoiding/changing exposure to cues for the behavior Behavioral experiments	- psychoeducation based on relatable case examples - differentiating eating types (e.g., restrictive eating) - CBT-based strategies to improve food-related inhibition (behavioral analysis)[8], [25] **Version B:** - psychoeducation based on relatable gender-specific statistics, facts, data (e.g., dual process theory)[26] - Go/No-Go training (gamification) tailored to individual attractive high-caloric food to improve food-related inhibition [27]
- Self-efficacy is positively	*Self-efficacy Module*	- psychoeducation: general information about eating and	Self-monitoring of behavior Goal setting	**Version A:**

associated with weight management [28], [29] - Women and men that experienced successful long-term weight loss maintenance reported higher levels of self-efficacy [focus groups]* - Men with obesity experience weight-loss as a competition and a project against themselves, commitment to "masculine" hard work [focus groups]* +[20]		movement-specific self-efficacy - association between self-efficacy, goal-setting and weight management[8] - exercises to improve weight management-related self-efficacy based on Bandura's 4 sources of efficacy beliefs [30]	Review behavior goal(s) Social support (general) Modeling of the behavior Social comparison Focus on past success Verbal persuasion to boost self-efficacy	- focussing on improving mastery experiences (internal attribution) and social support - CBT-based strategies to improve sources of efficacy beliefs **Version B:** - Approach-Avoidance Training (gamification) to improve food-related self-efficacy and offering competitive challenges to implement changes in everyday life

* Results of qualitative content analyses based on focus groups with women (n = 18) and men (n = 12) with overweight or obesity.

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Chapter 4 | Study 3: Differential Effects of the Individualized Gender-Sensitive mHealth Intervention I-GENDO on Eating Styles in Individuals with Overweight and Obesity – a Randomized Controlled Trial

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The following paper was first published in *BMC Digital Health*

Seiferth, C.*, Färber, T.*, Pape, M., Schoemann, N., Dieberger, A., Schroeder, S., Herpertz, S., Wolstein, J., Steins-Loeber, S. (2023). Differential effects of the individualized gender-sensitive mHealth intervention I-GENDO on eating styles in individuals with overweight and obesity – a randomized controlled trial. *BMC Digital Health*, 1(46), https://link.springer.com/article/10.1186/s44247-023-00041-0

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Differential effects of the individualized gender-sensitive mHealth intervention I-GENDO on eating styles in individuals with overweight and obesity – a randomized controlled trial

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Abstract

Background Addressing cognitive behavioral factors is associated with a favorable development of eating styles (i.e., increased levels of restrained eating, decreased levels of external and emotional eating) in individuals with overweight and obesity. Research suggests that the use of digital interventions that consider gender aspects regarding prevalence, comorbidities, and weight-related behaviors could enhance existing treatment options. This randomized controlled trial aimed to evaluate the effectiveness of the self-guided gender-sensitive mobile health intervention I-GENDO on restrained, emotional and external eating, body mass index, and physical activity at the end of the intervention, and at a 9- and 15-month follow-up.

Methods Two hundred thirteen individuals (67% female, body mass index: 33.35 ± 3.79 kg/m^2) were randomly assigned to the intervention or control group. Multilevel models were calculated to investigate differences between groups. I-GENDO offered interactive modules addressing psychological content associated with obesity. Users were able to self-tailor intervention content based on their individual needs and life realities.

Results Restrained eating was higher in the intervention group after the intervention (95% CI: 0.20, 0.36) and at 9-months (95% CI: 0.07, 0.24). At 9-months, emotional eating among women was lower in the intervention group compared to the control group (95% CI: -0.44, -0,19). In the intervention group, external eating was lower after the intervention, which remained significant for women at 9 (95% CI: -0.40, -0.19) and 15-months (95% CI: -0.34, -0.13). Body mass index of men in the intervention group was 1.44 lower at 15-months than in the control group. No significant effects on physical activity were found.

Conclusions The I-GENDO intervention was effective in changing restrained eating of both women and men in the long-term, suggesting that a self-guided, gender-sensitive approach is promising. However, the differential

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effects on the outcome measures indicate that more research is warranted to examine distinct gender-sensitive mechanisms of digital psychological interventions (i.e., dose–response relationship, blended counselling).

Trial registration ClinicalTrials.gov identifier: NCT04080193, 06–09-2019.

Keywords Obesity, Overweight, mHealth, Digital health, Psychology, Cognitive behavioral therapy, Gender

Background

A constant increase in body weight has been observed over the last few decades. Global prevalence rates estimate that in 2015, 1.9 billion adults worldwide were classified as overweight (body mass index, BMI: ≥ 25.00 kg/m^2) of which 609 million were affected by obesity (BMI ≥ 30.00 kg/m^2) [1]. The prevalence of overweight is approximately similar for women (38%) and men (37%), but women are more often affected by obesity (15%) than men (10%) [2]. Compared to men, women with overweight experience higher levels of weight discrimination [3] and weight dissatisfaction [4]. These experienced consequences tend to result in women initiating weight loss attempts more frequently than men [4], which increases the likelihood of weight-cycling and thus weight regain [5]. Overweight is associated with numerous adverse physical, psychological, and behavioral health outcomes. In addition to the short- and long-term physical health risks [6], individuals with overweight are at higher risk to experience adverse mental health outcomes such as depression and anxiety, lower self-esteem, body dissatisfaction, and self-efficacy [7, 8].

Eating styles, such as restrained, emotional and external eating, are known to be associated with weight loss and weight loss maintenance in individuals with overweight [9–11]. Restrained eating [12], that is, restricting food intake because of weight concerns, facilitates successful weight loss and weight loss maintenance [11]. In contrast, higher levels of reported emotional eating [12], that is, eating because of emotional states, such as anger or sadness, seem to present a barrier to weight loss [10, 13, 14] and pose a risk factor for weight regain after treatment [15]. The findings are inconclusive in studies investigating the impact of external eating [12], that is, eating because of external cues such as the sight or smell of food. Some studies found high external eating to be a barrier for long-term weight changes [9, 16], whereas some authors state that the extent of the influence of external eating on weight development is negligible [17].

These three eating styles are associated with different cognitive, emotional and behavioral abilities. For example, to successfully engage in restrained eating, a certain degree of self-control [18] and self-efficacy [19, 20] is necessary. Emotional eating often results from a lack of alternative coping strategies or emotion regulation skills needed for dealing with negative emotions or stressful situations [21–23]. To be able to regulate nutrition intake based on physiological internal (i.e., hunger, satiety) instead of external cues (i.e., time of day, smell of a certain food), the ability to identify the underlying motivation for eating as well as a certain degree of food-related inhibitory control is needed [24, 25].

Studies comparing individuals with overweight with normal weight counterparts have shown that the psychological abilities described above differ between these two groups. More specifically, individuals with overweight show deficits in inhibitory control [26, 27], emotion regulation [28], and interoceptive awareness [29, 30]. Moreover, an enhanced reactivity to food cues is prevalent in this group [31]. These underlying psychological abilities can be addressed and augmented through treatment components of cognitive-behavioral therapy (CBT) for obesity, such as emotion regulation skills training, problem solving, cognitive restructuring, stimulus control training, and mindfulness interventions [32]. Implementing CBT is associated with short-term weight loss [33] and a favorable development of eating styles [34–36].

Cognitive-behavioral factors leading to and maintaining excess weight can strongly vary between individuals. A growing body of research suggests gender disparities in weight-related attitudes and psychological mechanisms arising from sociocultural and behavioral aspects of overweight that differ between gender [4, 5, 37, 38]. For example, across all weight categories, women are more likely to perceive their weight as higher than it actually is [39] and to experience higher levels of internalized weight bias [40], whereas men tend to have an inaccurate weight perception in the opposite direction [4, 39]. Furthermore, women are more likely to ruminate [41] and men are more likely to engage in thought suppression [42], both characterizing unfavorable cognitive emotion regulation strategies for the development of problematic eating behaviors. Therefore, gender-specific needs and life-realities need to be identified and integrated into treatment of overweight to target intervention content and enhance efficacy.

Such individualization can be implemented through tailored mobile health (mHealth) interventions [43]. Customization of intervention content can be achieved by self-tailoring (i.e., users actively select the content that matches their preferences and needs) and/or computer-based tailoring (i.e., an algorithm processes data

entered by users and assigns the most suitable intervention content) [44–46]. A recent meta analysis indicated that tailoring lifestyle interventions with regard to gender is promising but more research in this field is needed [47]. Hence, we developed an initial gender-sensitive intervention approach that allowed users to actively select treatment content individually to their needs (i.e., self-tailoring) regardless of their biological sex [48].

Various mHealth interventions have been shown to be effective as a treatment option for overweight [49]. They present an effective way to provide low-threshold, personalized treatment solutions that deliver a combination of multiple evidence-based treatment components [50]. Most mHealth research focuses on changes in weight and total nutrition or calorie intake [51, 52]. Eating styles are often examined as relevant outcome measures or mediator variables for weight management in experimental and face-to-face studies, but mHealth studies investigating the development of eating styles are lacking. Therefore, we examined whether an mHealth intervention influences these eating styles in a similar fashion.

Against this background, the aim of the I-GENDO project was the development and evaluation of a gender-sensitive individualized psychological multi-component mHealth intervention with self-tailoring and computer-based tailoring elements [48, 53]. The goal of the 12-week mHealth intervention was to target eating styles by focusing on underlying psychological and behavioral aspects. The app provided CBT components within seven modules: goal setting and motivation, stress management skills, emotion regulation skills, dealing with consequences of overweight, self-efficacy, self-regulation skills, and relapse prevention. The study aimed to achieve short-term improvements in eating styles and also to faciliate long-term changes in physical activity and body compensation (i.e., BMI) by implementing beneficial psychological strategies through an individualized gender-sensitive treatment approach.

The efficacy of the I-GENDO app was evaluated in a randomized controlled trial (RCT) with a post assessment and two follow-ups at 9 and 15 months. The primary aim was to enhance restrained eating and to reduce emotional and external eating (primary outcomes) over the course of the intervention and follow-up period. In the intervention group, we expected a greater decrease in emotional and external eating and an increase in restrained eating compared to the control group. Furthermore, we assumed long-term improvements in physical activity levels and a decrease in BMI in the intervention group compared to the control group (secondary outcomes).

Methods

The study is reported in line with the CONSORT reporting guidelines ([54]; Additional file 1).

Study design

The efficacy of I-GENDO was assessed in a RCT (NCT04080193; 06–09-2019; Additional file 2) with a wait-list control condition. Data was collected before the onset of the I-GENDO intervention (baseline), at 3 months (end of intervention), 9 months (follow-up 1) and 15 months (follow-up 2) after baseline. At each of these four assessments, participants answered an extensive online questionnaire and wore an accelerometer for seven consecutive days. The study was carried out in accordance with the Declaration of Helsinki. The Ruhr-University Bochum Institutional Review Board (No. 18–6415) as well as the ethics committee at the University of Bamberg approved this study. All participants were informed about the study and provided informed consent.

Participants

Participants were recruited from August 2019 to August 2020 via study flyers, newspaper articles, social media, radio features, and oral presentations at weight loss rehab centers and clinical facilities. Participants interested in study participation were asked to complete an online survey to assess inclusion criteria and screen for exclusion criteria.

Participants were included if they a) were at least 18 years old; b) had a BMI between 30.00 and 39.99 kg/m^2 or a BMI between 25.00 and 29.99 kg/m^2 with weight-related health problems (e.g., type 2 diabetes, hypertension) or psychosocial distress; c) had access to a smartphone; d) were able to read, write and speak in German; and e) were motivated to lose weight. The latter was assessed by a single dichotomous item ("Do you currently intend to reduce your weight?", yes/no). Exclusion criteria were a) current pregnancy; b) current (or within the last 12 months) involvement in a structured psychological weight loss program; c) current psychotherapeutic treatment of weight-related problems; d) previous or intended bariatric surgery; e) current regular intake of drugs that influence weight; f) untreated weight-related health problems (e.g., hypothyroidism, chron's disease, dyslipidemia); g) current substance abuse, major depression or suicidal ideation; h) binge eating disorder or bulimia nervosa according to DSM-5 criteria; and i) severe cognitive impairments. In case of reported suicidal intentions assessed with the PHQ-9 [55] or suspected eating disorder assessed with the Munich ED-Quest [56], individuals

were contacted via phone and subsequently diagnosed with structured interviews by experienced psychologists and eventually referred to suitable support services.

A total of 675 individuals completed the survey, of which 363 were excluded because they met at least one exclusion criterion, and 99 individuals could not be reached or lost interest in study participation. Finally, 213 eligible participants were included in the study. All participants were randomly assigned to one of the study arms, stratified by gender: I-GENDO intervention ($n=116$, $n_{female}=77$) or control condition ($n=97$, $n_{female}=66$), using a computerized electronic random number generator. The majority of the participants identified themselves as female ($n=143$), 70 as male, and none as third gender.

An a priori power calculation revealed the need for $n=64$ participants per group to discover a medium effect of group differences ($\alpha=0.05$, 1-ß = 0.80). Dropout rates of 10% for each of the four assessments were expected, leading to a total of $N=214$ participants needed to be recruited. We initially obtained 214 randomized participants, but one person withdrew from the study and requested deletion of data, resulting in a final analytic sample of 213 participants. See Fig. 1 for the CONSORT flow diagram.

Procedure

Participants were invited to an in-person appointment at the study site in Bochum or Bamberg, Germany, where they received instructions about the procedure of the trial, installed the I-GENDO app on their personal smartphones (iOS or Android operating systems), answered questionnaires and received an accelerometer. Study staff was blinded to the group allocation of participants. The in-person appointments (i.e., study enrollment) were conducted between December 2019 and August 2020).

Participants were instructed to wear the accelerometer for seven consecutive days. After this assessment period, they were informed about their group allocation by e-mail. The interface of the app automatically switched from assessment mode (i.e., self-monitoring) to the control (i.e., number of days until the second questionnaire is available) or intervention (i.e., number of days until the intervention content is available) mode. On the next following Monday, the I-GENDO intervention was released to the intervention group. Participants in the control group received no intervention. After 3 months, both groups received the invitation to the second questionnaire, and the app interface switched back automatically to the assessment mode for all participants, based on their individual start day. Given the restrictions caused by the COVID-19 pandemic, no further in-person assessments could be conducted. Therefore, participants received instructions by phone or mail, and accelerometers for the 7-day assessment period were sent by mail. This procedure was identical for the 9- and 15-month follow-up assessments (Fig. 2). Data was collected from December 2019 to November 2021.

All participants received a monetary compensation of a maximum of 100€ for each of the four assessments resulting in a maximum of 400€ each (30€ for completing the questionnaire, 10€/day for wearing the accelerometer for at least 10 h). After completion of the last assessment (15 months after baseline) all participants in both the intervention and control were granted access to the I-GENDO intervention.

Intervention

The I-GENDO app is a 12-week self-guided multicomponent mHealth intervention that offered an individualized training program with seven modules primarily based on a CBT approach. The personalized assignment of the modules was based on the illness perceptions of each participant, measured by an adapted German version of the Illness-Perception Questionnaire (IPQ-R; [57, 58]). Individualization was implemented through self- and computer-based tailoring features. A detailed description of the I-GENDO intervention has been published previously [48].

The modules focused on different cognitive, emotional, and behavioral aspects related to weight loss management. These were a) goal setting and motivation; b) stress management skills; c) emotion regulation skills; d) dealing with consequences of overweight such as stigmatization and body dissatisfaction; e) self-efficacy; f) self-regulation skills; and g) relapse prevention. The modules were each offered in a female-targeted and a male-targeted version, which differed in terms of prioritization of topics, knowledge transfer, and communication style [48]. Participants were able to self-select one of the two offered module variations. They received a detailed description about the respective module content, but were not aware that the variations were based on a gender-specific rationale. Therefore, intervention content was not assigned due to biological sex or gender, but was assumed to be based on allignments with one's interests (i.e., gender-sensitive approach). This gender-sensitive approach was implemented to increase the relevance and appeal of each topic to all participants. A report about which gender variation was selected in the intervention group was published previously [48].

The training sessions within each module contained psychoeducational elements delivered through texts and videos and instructions for self-reflective and practical exercises (i.e., mindfulness exercises, behavioral rehearsal, self-monitoring of behavior, and social

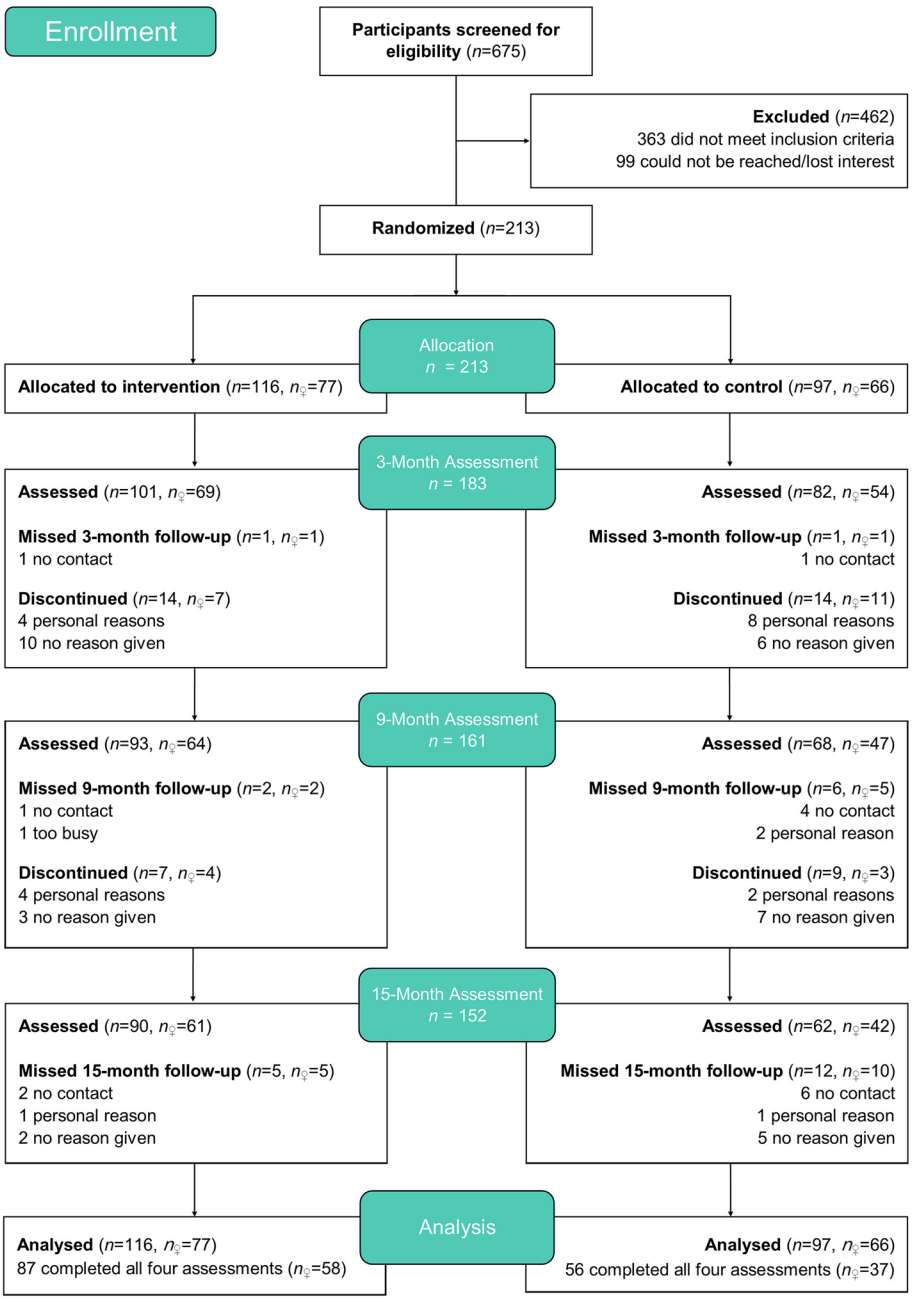

Fig. 1 CONSORT flow diagram of the randomized controlled trial. *Note.* *n* = indicates the total number of participants included/excluded in the respective group at the respective point in time; *n*♀ = indicates the total number of female participants included/excluded in the respective group at the respective point in time

support). The modules were unlocked continuously over the course of 12 weeks. Additionally, the app included optional functions such as self-monitoring, homework sessions, and a toolbox to save favored items.

Measures

Questions about age, gender, and anthropometry (i.e., weight, height) were included in the online questionnaires. BMI was calculated by dividing the reported body weight in kilograms by height in meters squared.

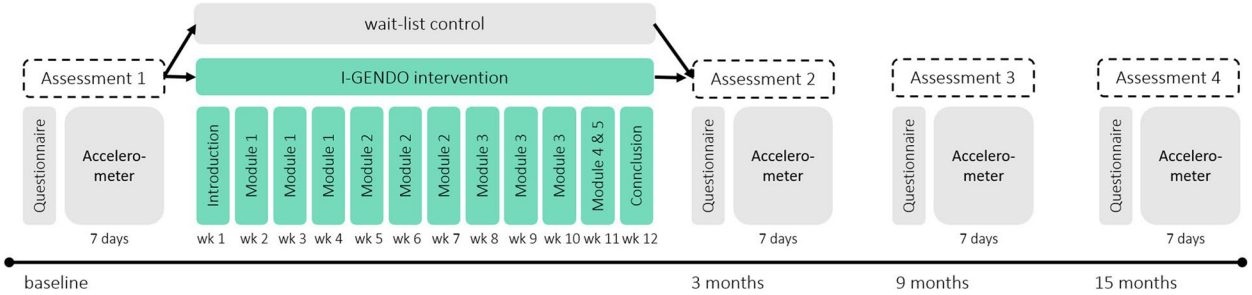

Fig. 2 Intervention procedure and assessments

Eating styles

The German version of the Dutch Eating Behaviour Questionnaire (DEBQ; [12, 59]) was used to assess eating styles. The questionnaire consists of 30 items with three subscales: emotional eating (i.e., eating because of different emotional states, such as anger or sadness), restrained eating (i.e., restricting food intake because of weight concerns) and external eating (i.e., eating because of external cues, such as the sight or smell of delicious food). Participants recorded their degree of agreement to each statement from 1 (never) to 5 (very often). Mean scores for each subscale were calculated. Higher values indicate a stronger expression of the corresponding eating style.

Device-based measured physical activity

Physical activity (i.e., step count) was measured continuously over the course of the four 7-day assessment periods using the tri-axial ActiGraph® wGT3X-BT accelerometer (firmware v1.9.2, ActiGraph, Pensacola, FL, USA), which was attached to an elastic waist belt. Participants were instructed to position the sensor on the right hip, which was found to be a good placement for the assessment of everyday physical activity [60]. Participants were instructed to wear the accelerometer during waking hours for seven consecutive days and to only take it off while showering or participating in other water-related activities. Raw data was sampled at an input frequency of 30 Hz and initially stored on the device. The ActiLife® software (version 6.13.4; ActiGraph, Pensacola, FL, USA) was used to process the raw data into meaningful step count. Participants were required to provide at least 10 h of wear time per day (valid day) for at least four days in each assessment week to be included in the analysis. Average step count per day was calculated by dividing the total amount of steps of valid days by the number of valid days.

Statistical analyses

Descriptive analyses were conducted using percentages and frequencies for categorical variables, as well as means and standard deviations for continuous variables. Comparisons of socio-demographic variables and baseline values between the intervention and control group and between male and females within each group were tested using chi-square distributions (categorical) and analyses of variance (ANOVA; continuous variables). Linear multilevel regression models were estimated using maximum likelihood to analyze the impact of the intervention (i.e., I-GENDO, control), time (i.e., baseline, 3, 9 and 15 months), gender (female, male) and the intervention-by-time interaction. A two-level model structure including a random intercept was applied. To examine the specific intervention effect on each outcome, five separate models were specified for each dependent variable (restrained, emotional, and external eating, BMI, step count). All reported models were adjusted for the baseline value of the outcome variable (see Additional file 3 for models without adjustment of baseline values). Mean values of each outcome were estimated at 3, 9 and 15 months for both groups and differences between the intervention and control group were calculated.

To test for potential effect modification by gender, group*time*gender interaction terms were added to the models, and the interaction term remained in the final model when significant interactions with gender were detected, and estimates were reported separately for men and women. Intraclass correlation coefficients (ICCs) of the null models indicated that 62% (restrained eating), 79% (emotional eating), 75% (external eating), 91% (BMI), and 62% (step count) of the differences were due to between-person effects.

SPSS 28 (IBM Corp, Armonk, NY, USA) and different packages of R [61] and Rstudio [62] were used for all analyses. The 'ggplot2' package (v 3.3.5) was used for visualizations [63], multilevel models were calculated using the 'nlme' package (v. 3.1 – 155; [64]), and model assumptions were checked using the 'performance' package in R (c. 0.8.0; [65]). The results tables of the regression analyses were generated using the 'sjPlot'

package (v 2.8.10; [66]). Level for significance was set a priori to $p < 0.05$.

Results

No significant baseline differences in sociodemographic variables between the two study groups were detected (Table 1). However, women in the control group were significantly younger than men in the control group ($F(1, 209) = 7.07$, $p = 0.008$, partial $\eta^2 = 0.033$) and women in the control and intervention group reported significantly higher scores on the emotional eating scale than male participants in the respective groups ($F(1, 209) = 14.40$, $p < 0.001$, partial $\eta^2 = 0.064$). Significantly more individuals in the intervention group ($n = 87$) completed all four assessments than in the control group ($n = 56$; $\chi^2(1) = 6.38$, $p = 0.012$).

Table 2 displays the model-estimated means, standard errors, 95% confidence intervals (CI) and between-group difference at 3, 9 and 15-month assessments adjusted for baseline value from fitted maximum likelihood repeated measures mixed models for the self-reported outcomes.

Individuals in the intervention group reported significantly higher scores for restrained eating than participants in the control group at 3-month ($\beta = 0.47$, $p < 0.001$) and 9-month ($\beta = 0.26$, $p = 0.033$) assessment. As shown in Table 2, the difference was 0.28 at 3 months (95% CI: 0.20, 0.36) and decreased towards 0.15 at 9 months (95% CI: 0.07, 0.24). Although higher values were reported by the intervention group compared to the control group after 15 months (difference: 0.13, 95% CI: 0.04, 0.22), this difference was only marginally significant ($\beta = 0.23$, $p = 0.069$). We found no gender differences in intervention effects.

A gender-specific effect of the intervention was found for emotional eating, as indicated by a significant interaction between group, time, and gender. Women in the intervention group reported significantly lower emotional eating at the 9-month assessment compared to women in the control group ($\beta = -0.34$, $p = 0.013$; difference -0.32, 95% CI: -0.44, -0.19). No significant differences were found immediately after the intervention (3 months; $\beta = -0.15$, $p = 0.260$) or in the long-term (15 months; $\beta = -0.23$, $p = 0.103$). Men reported no significantly different values across groups at any assessment, indicating that the intervention had no significant effect on emotional eating in men (all $ps > 0.10$).

Women and men in the intervention group reported significant lower levels of external eating than participants in the control group. Females in the intervention group reported decreased levels of external eating in comparison to the women in the control group at the end of the intervention (difference at 3 months: -0.20, 95% CI: -0.30, -0.10; $\beta = -0.26$, $p = 0.031$) and at follow-up (difference at 9 months: -0.29, 95% CI: -0.40, -0.19, $\beta = -0.39$, $p = 0.002$; difference at 15 months: -0.23, 95% CI: -0.34, -0.13; $\beta = -0.31$, $p = 0.017$). In males, external eating was only significantly lower in the intervention group immediately after receiving the intervention (difference at 3 months: -0.30, 95% CI: -0.45, -0.15; $\beta = -0.31$, $p = 0.016$).

Table 1 Baseline characteristics

Variables	Overall		Control		Intervention	
	Control ($n = 97$)	Intervention ($n = 116$)	Female ($n = 66$)	Male ($n = 31$)	Female ($n = 77$)	Male ($n = 39$)
Demographics						
Age (in years); *M* (*SD*)	45.45 (12.66)	47.27 (11.65)	43.24 (12.86)*	50.16 (11.00)	46.40 (12.22)	49.00 (10.38)
High School Degree; *n* (%)	25 (25)	36 (31)	17 (26)	8 (26)	25 (32)	11 (28)
Married or living with a partner; *n* (%)	79 (81)	91 (78)	52 (79)	27 (87)	57 (74)	34 (87)
Weight and body composition						
Weight (in kg); *M* (*SD*)	97.65 (14.84)	98.34 (15.39)	94.24 (13.43)	104.90 (15.31)	93.44 (12.56)	108.03 (16.02)
BMI (in kg/m^2); *M* (*SD*)	33.07 (3.79)	33.58 (3.79)	33.23 (3.74)	32.72 (3.92)	33.75 (3.69)	33.23 (4.02)
Eating Styles						
Restrained Eating; *M* (*SD*)	2.80 (0.58)	2.70 (0.58)	2.83 (0.58)	2.75 (0.58)	2.78 (0.55)	2.55 (0.62)
Emotional Eating; *M* (*SD*)	3.12 (0.95)	3.05 (1.03)	3.36 (0.86)***	2.59 (0.94)	3.30 (0.95)***	2.57 (1.02)
External Eating; *M* (*SD*)	3.47 (0.62)	3.48 (0.67)	3.54 (0.65)	3.33 (0.54)	3.52 (0.66)	3.42 (0.71)
Physical activity[a]						
Step count per day; *M* (*SD*)	7296 (3020)	6831 (2251)	7196 (2756)	7505 (3559)	6765 (1965)	6966 (2776)

BMI body mass index. Asteriks in column 4 (control/female) and column 6 (intervention/female) indicate significant baseline differences between female and male participants in the respective group. *$p < 0.05$, *** $p < 0.001$

[a] $n = 194$

Table 2 Model-estimated means, standard errors, and 95%CI for all outcomes at 3, 9 and 15 months

	3 months							9 months							15 months						
	Control			Intervention			Between-group difference [95% CI]	Control			Intervention			Between-group difference [95% CI]	Control			Intervention			Between group difference [95% CI)
	Mean	SE	95% CI	Mean	SE	95% CI		Mean	SE	95%CI	Mean	SE	95%CI		Mean	SE	95%CI	Mean	SE	95%CI	
Restrained																					
Overall	2.85	0.05	[2.76, 2.94]	3.13	0.04	[3.05, 3.21]	**0.28 [0.20, 0.36]**	2.85	0.05	[2.76, 2.95]	3.00	0.04	[2.92, 3.09]	**0.15 [0.07, 0.24]**	2.78	0.05	[2.68, 2.89]	2.91	0.04	[2.83, 3.00]	**0.13 [0.04, 0.22]**
Emotional[a]																					
Male	3.09	0.10	[2.89, 3.28]	2.94	0.09	[2.76, 3.12]	-0.15 [-0.33, 0.03]	2.88	0.11	[2.66, 3.10]	3.03	0.10	[2.84, 3.22]	0.14 [-0.05, 0.33]	2.97	0.12	[2.74, 3.19]	3.14	0.10	[2.95, 3.33]	0.17 [-0.02, 0.36]
Female	3.12	0.07	[2.98, 3.26]	2.98	0.06	[2.86, 3.10]	-0.14 [-0.27, -0.02]	3.34	0.08	[3.19, 3.49]	3.03	0.07	[2.90, 3.15]	**-0.32 [-0.44, -0.19]**	3.22	0.08	[3.07, 3.38]	3.01	0.07	[2.88, 3.14]	-0.22 [-0.35, -0.09]
External[a]																					
Male	3.47	0.08	[3.31, 3.63]	3.17	0.08	[3.02, 3.32]	**-0.30 [-0.45, -0.15]**	3.32	0.09	[3.14, 3.49]	3.37	0.08	[3.21, 3.52]	0.05 [-0.10, 0.20]	3.36	0.09	[3.17, 3.54]	3.22	0.08	[3.07, 3.37]	-0.14 [-0.29, 0.02]
Female	3.56	0.06	[3.45, 3.68]	3.37	0.05	[3.27, 3.47]	**-0.20 [-0.30, -0.10]**	3.57	0.06	[3.45, 3.69]	3.28	0.05	[3.17, 3.38]	**-0.29 [-0.40, -0.19]**	3.44	0.06	[3.32, 3.57]	3.21	0.05	[3.11, 3.32]	**-0.23 [-0.34, -0.13]**
BMI (kg/m2)[a]																					
Male	33.41	0.28	[32.86, 33.96]	32.58	0.26	[32.07, 33.09]	**-0.84 [-1.35, 0.33]**	33.74	0.32	[33.12, 34.36]	32.73	0.27	[32.20, 33.27]	**-1.00 [-1.54, -0.47]**	33.69	0.32	[33.05, 34.32]	32.25	0.27	[31.72, 32.78]	**-1.44 [-1.97, -0.91]**
Female	33.00	0.20	[32.61, 33.39]	32.83	0.18	[32.48, 33.18]	-0.17 [-0.52, 0.18]	32.88	0.21	[32.46, 33.29]	33.06	0.18	[32.69, 33.42]	0.18 [-0.18, 0.54]	32.63	0.22	[32.19, 33.06]	33.17	0.19	[32.80, 33.54]	0.54 [0.17, 0.91]
Step count/ day																					
Overall	6793.14	319.25	[6167.43, 7418.85]	6867.78	273.09	[6332.56, 7403.01]	74.64 [-460.58, 609.87]	6547.14	241.01	[6074.77, 7019.50]	6777.69	192.97	[6399.47, 7155.91]	230.56 [-147.67, 608.78]	6836.39	243.61	[6358.93, 7313.85]	7114.21	188.18	[6745.38, 7483.04]	277.82 [-91.01, 646.65]

Note. Bold text indicates significant between-group effects. Displayed are the results of the multilevel model analysis for each outcome (restrained eating, emotional eating, external eating, BMI, step count/day) adjusted for baseline value and assessment (3 months, 9 months, 15 months). Each model contained an interaction term for time*group and, in case the interaction was significant, an interaction for time*group*gender

[a] Estimates were reported separately for men and women if a significant group*time*gender interaction was detected

Compared with the control group, the assignment of the intervention resulted in a statistically significant long-term weight loss for men (difference at 15 months: -1.44, 95% CI: -1.97, -0.91; β = -0.36, $p < 0.001$). Immediately after the intervention the difference was -0.84 (95% CI: -1.35, 0.33; β = -0.21, $p = 0.016$) and increased to -1.00 BMI points (95% CI: -1.54, -0.47; β = -0.25, $p = 0.008$) at 9 months. The intervention had no significant effect on women's BMI. Figure 3 displays the between-group differences for each outcome at each assessment.

No baseline adjusted differences between men and women at 3 (74.64, 95% CI: -460, 609), 9 (230, 95% CI: -147, 608) and 15 months (277, 95% CI: -91, 646) were found between the intervention and control group for step count, indicating that the intervention had no effect on this physical activity measure (Additional file 4).

Discussion

The aim of this RCT was to investigate whether a gender-sensitive psychological mHealth intervention based on CBT improves eating styles by addressing the underlying psychological skills. Overall, our mHealth intervention achieved favorable long-term (15 months) changes in restrained eating for women and men and in external eating for women. Additionally, the I-GENDO intervention led to a statistically significant decrease in men's BMI.

Restrained eating

Our results show that men and women in the intervention group, compared to controls, showed improvements in restrained eating immediately after the intervention (three months after baseline), which were also observed at follow-up at 9-months and, with marginal significance at 15 months. This result is promising because in face-to-face intervention studies increased levels of restrained eating are known to be predictors of weight loss and weight loss maintenance [11] and related to long-term success [67]. Research also shows that restrained eating has a preventive effect on weight gain, even when eating habits that are normally associated with weight gain are prevalent, for example, loss of control eating [17].

Bijholt and colleagues [68] investigated women during the postpartum period with a history of excessive gestational weight gain using the INTER-ACT mHealth intervention in combination with face-to-face contact. They also found a favorable increase of restrained eating, but the effect was only short-term immediately after the intervention and was not evident at the 6 month follow-up [68]. In our study, the effect was still present at 9 months, and it was also present in men. While the general principles of the INTER-ACT intervention were goal setting and motivational tips [69], the I-GENDO intervention included highly interactive and

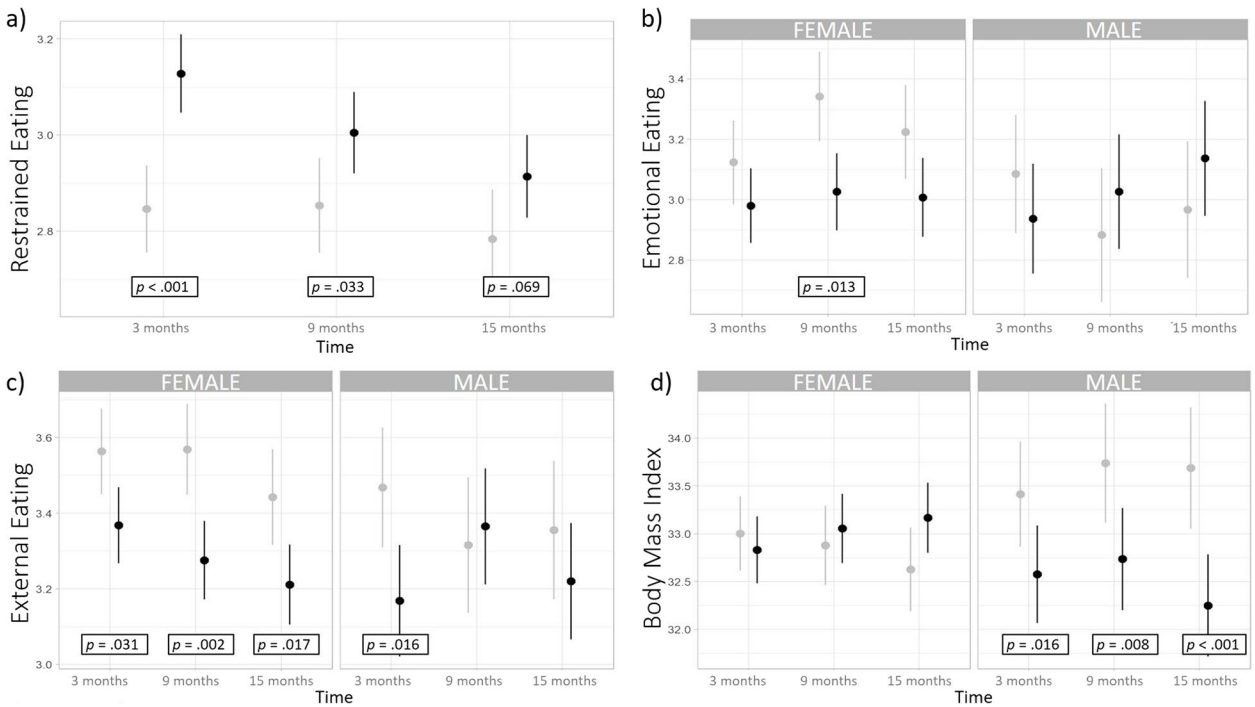

Fig. 3 Intervention effect for each outcome at each assessment. *Note.* Between-group differences (black = intervention group, gray = control group) adjusted for baseline value for **a**) restrained eating, **b**) emotional eating, **c**) external eating, **d**) BMI at each assessment for each gender. Significant ($p < .05$) and marginally significant interactions ($p < .10$) are indicated by the *p* value

cognitive demanding content for knowledge acquisition, self-reflection, and exercises for knowledge transfer. These behavior change techniques and components of CBT are also implemented in effective face-to-face studies addressing eating styles [36]. Overall, increasing restrained eating plays an important role in conventional obesity treatments, and we showed that these sustained effects can also be reached by using our I-GENDO mHealth intervention.

Emotional eating

Contrary to assumptions, the I-GENDO intervention elicited no long-term changes in emotional eating in either men or women. We only observed an effect after 9 months in women, which was not maintained at 15 months. This was unexpected because emotional eating is associated with a decreased ability to regulate emotions [70], and the intervention content was specifically designed to empower the participants to identify unfavorable emotion regulation strategies (i.e., eating to suppress feelings, rumination) and to adapt and build substantial emotional competences.

These findings may be related to the challenges posed by the digital implementation of emotion regulation strategies. CBT has been shown to be effective in the treatment of obesity in face-to-face settings [34]. Therefore, the I-GENDO intervention included several evidence-based CBT principles that targeted emotional competences (i.e., identify warning signs, build helpful habits, problem solving, and relaxation). Studies investigating the effects of self-guided digital interventions in non-clinical samples showed that the digital adaptation of CBT successfully led to favorable changes in stress, mindfulness, and eating behaviors [71, 72]. Nevertheless, a lack of studies have validated the effectiveness of CBT strategies that target emotion regulation in mHealth programs for the specific target group of individuals with overweight and obesity [73, 74]. Therefore, we question whether a self-guided mHealth environment represented a feasible approach to substantially change emotional processes in emotionally burdened individuals as in the present sample. These considerations are particularly reasonable in light of the fact that meaningful differences in restrained eating were elicited by the I-GENDO intervention. In such conditions, the cognitive approach of an mHealth intervention may be more suitable because restrained eating behavior is associated with predominantly cognitive processing (i.e., goal activation) and executive functions (i.e., inhibition control) [75, 76]. Thus, we assume that to significantly change emotional strategies an individualized blended intervention approach or even a face-to-face setting is needed.

Another possible explanation for the lack of long-term changes in emotional eating might be that participants differ in the level of knowledge and awareness about the effects of emotions on eating. Thus, participants who have less access to their emotions might need more support and time gaining insight into emotions and possibly need more time practicing new emotion regulation skills, whereas those aware of their emotions and individual emotion-regulation skills could find cognitive restructuring more helpful [77]. A noteworthy consideration is that the time and dose offered by the I-GENDO intervention was not sufficient to change emotional processes. Our results suggest that access to own emotions, emotion regulation strategies already used, and the degree of trait emotional intelligence should be assessed before the beginning of the intervention [21]. The intervention should then be adapted accordingly to the affect-related psychological needs of the person.

External eating

The intervention was effective for female participants immediately after the intervention and at both 9-month and 15-month assessment compared to the control group. In contrast to our expectations, we observed an intervention effect for male participants only immediately after the intervention, not at the 15-month follow-up. A pronounced external eating style is associated with a reduced ability to perceive internal bodily cues (i.e., hunger, satiety) [78] and a higher attentional bias for food cues [24, 79]. Furthermore, external eating is associated with overconsumption [17], binge eating [80], and food craving [16].

A review of mHealth interventions in obesity treatment that focus on changing external eating showed that such interventions focus predominantly on promoting mindfulness-based eating awareness. This strategy is considered as an antagonist of external eating because it represents the ability to perceive internal signals (i.e., hunger, satiety) and to guide eating behavior accordingly [81]. The main criticism of the reviewed studies was that the key features of the apps (i.e., eating timers, hunger rating apps, diaries) were not sufficient to establish a mindfulness-based eating style. In contrast, our multibehavioral I-GENDO intervention offered more comprehensive and diverse features developed to teach mindful eating as an alternative strategy to external eating (i.e., guided eating meditations, strategies involving the five senses, integration of mindfulness into daily life). These aspects might explain why participants in our study had favorable values in external eating immediately after the end of the intervention. However, an interesting finding is that the effect was not maintained for men. We assume that women benefitted in the long-term because

they might have adopted the strategies and mindset into their everyday life. This is reasonable since research indicates that women tend to benefit more from mindfulness interventions than men [82].

BMI and physical activity

Our intervention led to a small but sustained BMI decrease in men, which was statistically significant but not clinically relevant (< 5% weight loss). Furthermore, we found no improvements in physical activity in the intervention group for men and for women. The I-GENDO intervention primarily sought to change psychological aspects of eating behavior and eating styles. We had no assumptions that our intervention would have a short-term impact on weight or exercise behavior because we prescribed no specific nutritional or activity recommendations (such as low-fat diet or minimum step count). However, we assumed that BMI would decrease and that physical activity would increase in the long-term. We hypothesized that learned psychological skills and strategies such as goal setting might also affect physical activity and that improving eating styles would also affect weight development, but we found no evidence for these effects. Apparently, working primarily on psychological factors associated with weight management had no clinically relevant effect on BMI or physical activity in the long-term. However, mHealth studies that have provided specific behavioral instructions also show only ambiguous or inconsistent results on the clinical relevance of weight loss or long-term effects [83].

Perhaps an mHealth intervention would be more beneficial on the BMI or physical activity, if an individualized CBT-based mHealth approach was combined with concrete behavioral suggestions such as calorie restrictions or a daily exercise goal. Just-in-time-interventions that offer treatment strategies tailored to the actual behavior show promising results for increasing physical activity [84]. However, a stand-alone self-guided mHealth intervention might not be sufficient enough to substantially change behavioral outcomes and perhaps should therefore be combined with traditional face-to-face approaches.

Limitations and strengths

Our study has some noteworthy limitations. First, the significant differences in attrition rates between the control and intervention group represent a weakness of the study (dropout rates: 42% vs. 25%). Although participants in the control group were given access to the app after the end of the study, and the financial incentives were the same for both groups, being assigned to the control condition during this phase of behavior change (i.e., motivation to lose weight, high expectancies) could have understandably elicited frustration and contributed to a higher dropout. This phenomenon has also been observed in comparable mHealth RCTs [85]. We considered these differences by implementing a multilevel model approach, which is robust to the biases of missing data and represents an intention-to-treat approach [86]. Second, we verified that all participants were motivated to reduce weight, but since no validated questionnaire was used, we cannot explore the extent to which specific motivations for weight loss (i.e., health, appearance, social pressure) have affected study participation. Third, our app allowed users to independently select one of two gender-specific variants for each module and was thus gender-sensitive (self-tailoring). Although this innovative technological approach is very promising because of the established sex differences in obesity treatment, the lack of a comparison group with a non-gender-sensitive app precludes the conclusion that this gender-sensitive structure contributed to greater effects. This comparison still needs to be verified in future studies.

Moreover, this study was conducted over the course of the COVID-19 pandemic. Due to the different times of study enrollment and data assessment periods, it is not possible to systematically investigate whether or to what extent different restrictions in the different parts of Germany may have influenced the study implementation and results. This should be noted as a potential influencing factor, as there are recent studies showing that the pandemic had an impact on various health behavior [87, 88]. Furthermore, the periodic contact restrictions have hindered the objective collection of anthropometric data at the study sites.

A strength of the current study is that the development of the I-GENDO intervention was guided by a participative and iterative research process, actively involving patients as well as experts in the treatment of obesity. Overall, the intervention was well received by the participants [48] and compared to other lifestyle mHealth self-monitoring intervention groups (range: 5%—55%), we observed a relatively low drop-out rate in the intervention group (25%) by the 15 month [89]. Most interventions in obesity treatment do not take different gender preferences into account [90]. Therefore, we developed a gender-sensitive, computer- and self-tailored intervention, which reflects an attempt to integrate a gender-sensitive approach. Our results show that we succeeded in designing a self-guided mHealth approach, that targets women and men, which results in differential but favorable effects for both genders.

Conclusion

This study demonstrated that the gender-sensitive multi-component self-guided mHealth intervention I-GENDO provides long-term benefits from restrained eating for women and men with overweight and obesity who are motivated to lose weight but not from emotional eating and only beneficial changes in external eating for women. We assume that restrained eating might be feasible to target with a CBT-based mHealth approach because it is associated with more cognitive processes that can be implemented and modified in a self-guided matter. In contrast, emotional processes that are associated with emotional eating might be better addressed via blended counseling approaches because they allow a more profound examination and interaction with these topics in face-to-face settings. For BMI and physical activity, the stand-alone I-GENDO intervention elicited no clinical meaningful effects. Therefore, we recommend our gender-sensitive mHealth intervention especially when the focus is on changing restrained eating behavior (i.e., individuals with decreased food-related inhibitory control). For further outcome measures associated with weight management, like emotional eating, BMI, and physical activity, our app is not sufficient alone and can therefore be recommended as a valuable add-on treatment in combination with a face-to-face intervention.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s44247-023-00041-0.

Additional file 1. Reporting checklist for randomized trial.

Additional file 2. Content of the PRE-registration.

Additional file 3: Table A1. Model-estimated means, standard errors, and 95%CI for the self-reported outcomes at 3, 9 and 15 months, not adjusted for baseline value.

Additional file 4: Figure A1. Intervention effect for the physical activity outcome at each assessment.

Acknowledgements

We are very grateful to all participants who took part in the I-GENDO study. We further want to thank Theresia Morgenroth and all involved student assistants for research assistance. Special thanks to our project partners at groupXS Solutions GmbH (https://www.groupxs.com/) for the implementation of the mHealth intervention and their technical support. We also would like to thank Professor Dr. Michael Cofrin for the language editing of the manuscript. The authors acknowledge support by the Open Access Publication Fund of the University of Bamberg.

Authors' contributions

CS, TF, MP, SS, JW, SSL, and SH designed the study. CS, TF, and MP collected the data, and formulated the study question. CS, TF, NS, and AD performed the data analysis, data interpretation, and generation of figures and tables. JW was responsible for preparing the accelerometer data for statistical analysis. CS, TF, and NS drafted the manuscript. JW, MP, AD, SH, and SSL contributed to the final version of the manuscript. All authors reviewed and approved the final manuscript.

Authors' information

Not applicable.

Funding

Open Access funding enabled and organized by Projekt DEAL. This work is part of the project "Gender-sensitive enhancement of common weight loss strategies for overweight and obesity: A personalized smartphone app" (I-GENDO) funded by a grant from the Federal Ministry of Education and Research (BMBF; grant no. 01GL1719A and 01GL1719B). The funding body was neither involved in the design of the study, data collection, analysis, interpretation of data nor in writing the manuscript.

Availability of data and materials

The intervention content used and the datasets analysed during the current study available from the corresponding author on reasonable request. Analysis code is available at the Open Science Framework (https://osf.io/r4p9d/#).

Declarations

Ethics approval and consent to participate

The study was carried out in accordance with the Declaration of Helsinki. The Ruhr-University Bochum Institutional Review Board (No. 18–6415) as well as the ethics committee at the University of Bamberg approved this study. All participants were informed about the study and provided informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 20 March 2023 Accepted: 4 September 2023
Published online: 09 November 2023

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Publisher's Note

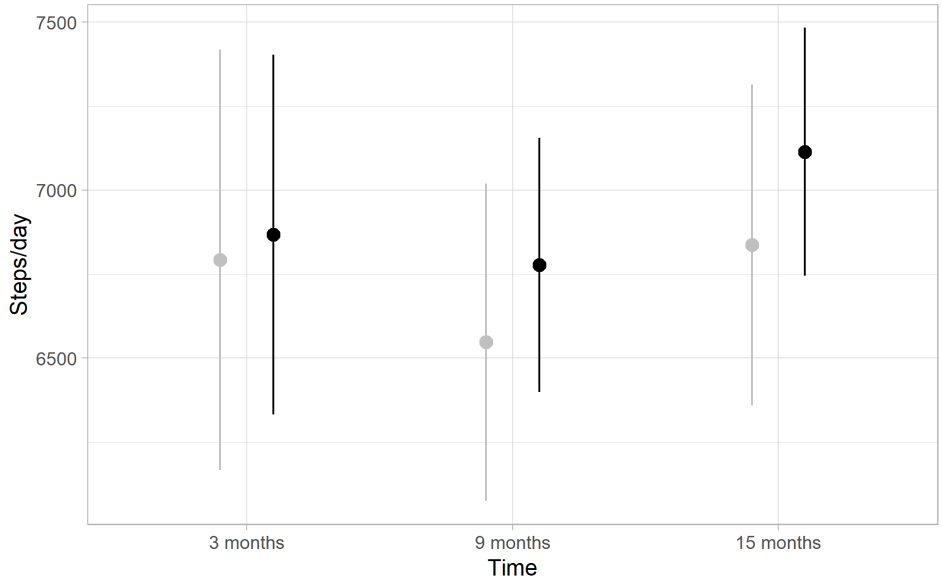
Table A1 Model-estimated means, standard errors, and 95%CI for the self-reported outcomes at 3, 9 and 15 months, not adjusted for baseline value.

	3 months							9 months							15 months						
	Control			Intervention			Between-group difference [95% CI]	Control			Intervention			Between-group difference [95% CI]	Control			Intervention			Between group difference [95% CI)
	Mean	SE	95% CI	Mean	SE	95% CI		Mean	SE	95%CI	Mean	SE	95%CI		Mean	SE	95%CI	Mean	SE	95%CI	
Restrained																					
Overall	2.89	0.07	[2.76, 3.01]	3.10	0.06	[2.98, 3.22]	**0.20 [0.08, 0.32]**	2.91	0.07	[2.77, 3.05]	2.98	0.06	[2.86, 3.10]	**0.07 [-0.05, 0.19]**	2.83	0.07	[2.68, 2.97]	2.88	0.06	[2.76, 3.00]	**0.54 [-0.07, 0.18]**
Emotional																					
Male[1]	2.67	0.17	[2.34, 3.00]	2.52	0.15	[2.22, 2.82]	-0.16 [-0.46, 0.15]	2.46	0.18	[2.11, 2.81]	2.60	0.16	[2.29, 2.91]	0.14 [-0.17, 0.45]	2.56	0.18	[2.21, 2.91]	2.71	0.16	[2.41, 3.02]	0.15 [-0.16, 0.46]
Female	3.36	0.12	[3.13, 3.59]	3.17	0.11	[2.96, 3.38]	-0.19 [-0.40, 0.02]	3.55	0.12	[3.32, 3.79]	3.21	0.11	[2.99, 3.42]	**-0.35 [-0.56, -0.13]**	3.47	0.12	[3.22, 3.71]	3.19	0.11	[2.98, 3.41]	-0.28 [-0.49, -0.06]
External																					
Male[1]	3.32	0.13	[3.07, 3.58]	3.11	0.12	[2.87, 3.34]	**-0.21 [-0.45, 0.02]**	3.16	0.14	[2.89, 3.44]	3.30	0.12	[3.06, 3.54]	0.13 [-0.10, 0.37]	3.19	0.14	[2.92, 3.47]	3.16	0.12	[2.92, 3.39]	-0.03 [-0.27, 0.02]
Female	3.61	0.09	[3.43, 3.79]	3.39	0.08	[3.24, 3.56]	**-0.22 [-0.38, -0.05]**	3.61	0.09	[3.43, 3.79]	3.30	0.14	[3.14, 3.46]	**-0.31 [-0.48, -0.14]**	3.50	0.09	[3.31, 3.69]	3.25	0.09	[3.08, 3.42]	**-0.25 [-0.42, -0.09]**
BMI (kg/m2)																					
Male[1]	32.78	0.73	[31.34, 34.22]	32.44	0.65	[31.15, 33.74]	**-0.34 [-1.63, 0.95]**	33.04	0.75	[31.57, 34.52]	32.56	0.66	[31.26, 33.87]	**-0.48 [-1.79, -0.82]**	32.96	0.75	[31.49, 34.44]	32.08	0.66	[30.77, 33.38]	**-0.89 [-2.19, 0.42]**
Female	32.95	0.50	[31.96, 33.94]	33.28	0.46	[32.36, 34.19]	0.32 [-0.58, 1.24]	32.80	0.51	[31.80, 33.81]	33.50	0.46	[32.59, 34.42]	0.70 [-0.22, 1.62]	32.60	0.51	[31.59, 33.61]	33.61	0.46	[32.69, 34.53]	1.01 [0.09, 1.93]
Step count/ day																					
Overall	6868.89	403.82	[6077.41, 7660.36]	6559.34	355.04	[5863.46, 7255.21]	-309.55 [-1005.42, 386.32]	6717.74	333.62	[6063.85, 7371.63]	6613.26	284.84	[6054.99, 7171.54]	-104.47 [-662.75, 453.80]	7117.39	335.84	[6459.15, 7775.63]	6997.36	279.77	[6449.02, 7545.70]	-120.02 [-668.36, 428.31]

[1] Estimates were reported separately for men and women if a significant group*time*gender interaction was detected.

Note. Bold fond indicate significant between-group effects. Displayed are the results of the multilevel model analysis for each outcome (restrained eating, emotional eating, external eating, BMI, step count/day) and assessment (3 months, 9 months, 15 months). Each model contained an interaction term for time*group and, in case the interaction was significant, an interaction for time*group*gender.

Figure A1. Intervention effect for the physical activity outcome at each assessment.



Legend. Between-group differences (black = intervention group, gray = control group) adjusted for baseline value for step count per day at each assessment.

Chapter 5 | Study 4: How to e-mental Health: A Guideline for Researchers and Practitioners Using Digital Technology in the Context of Mental Health

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Seiferth, C.*, Vogel, L.*, Aas, B., Brandhorst, I., Carlbring, P., Conzelmann, A., Esfandiari, N., Finkbeiner, M., Hollmann, K., Lautenbacher, K., Meinzinger, E., Newbold, A., Opitz, A., Renner, T. J., Sander, L. B., Santangelo, P. S., Schoedel, R., Schuller, B., Stachl, C., sysTelios Think Tank, Terhorst, Y., Torous, J., Wac, K., Werner-Seidler, A., Wolf, S. & Löchner, J. (2023). How to e-mental health: a guideline for researchers and practitioners using digital technology in the context of mental health. *Nature Mental Health*, 1, 542 – 554. https://doi.org/10.1038/s44220-023-00085-1

How to *e-mental Health*? A Guideline for Researchers and Practitioners using Digital Technology in the Context of Mental Health

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ABSTRACT

Objective. Despite an exponentially growing number of digital or e-mental health services, methodological guidelines for research and practical implementation are scarce. We aim to

promote methodological quality, evidence, and long-term implementation of technical innovations in the healthcare system.

Method. This expert consensus is based on an iterative Delphi adapted process and provides an overview of the current state-of-the-art guidelines and practical recommendations of the most relevant topics in e-mental health assessment and intervention.

Results. Covering three objectives i) development, ii) study specifics, iii) intervention evaluation, 11 topics were addressed and co-reviewed by 25 international experts and 1 think tank in the field of e-mental health.

Conclusion. As the first of its kind, this expert consensus provides a comprehensive essence of scientific knowledge and practical recommendations for e-mental health researchers and clinicians. This way, we aim to enhance the promise of e-mental health: a low-threshold access to mental health treatment worldwide.

INTRODUCTION

Mental illness is on the rise, and since the COVID-19 Pandemic, prevalence rates have significantly increased[1]. At the same time, healthcare systems around the world are challenged to provide adequate psychological help due to several (individual and social) barriers and challenges. These challenges include health disparities, insufficient infrastructure, workforce shortage, long waiting lists[2], stigmatization, and low perceived need[3]. The COVID-19 outbreak also resulted in an unexpected acceleration of digitalisation in different fields[4], as well as in the increased efforts in prevention, treatment and rehabilitation of mental disorders. There are numerous advantages that *e-mental health* may offer: low-threshold access, geographic independence, constant availability, and potentially lower cost[5].

Despite the increase and numerous advantages of e-mental health solutions, several shortcomings affect the development and delivery of e-mental health interventions. Firstly, therapists are still skeptical of prescribing digital mental health care because they perceive themselves as not sufficiently trained in this area and lack knowledge about which technologies are validated and affordable for various patient groups[6]. Furthermore, uncertainty exists regarding the impact that digital approaches might have on the therapeutic relationship[7]. Secondly, among other challenges (e.g. not being familiar with new technological developments), users face difficulties in distinguishing scarcer, evidence-based interventions among the plethora of health and well-being offers[8]. Thirdly, the field of research is also inconsistent regarding terminology[1], leading to miscommunication with users and stakeholders[9]. Finally, guidance and methodological advancements are not only necessary to improve user experience, but also to raise quality standards in development and evaluation. In meta-analytical reviews, most e-mental health apps were shown to perform badly regarding data security and transparency[10], methodological quality, and attrition rates[11]. However, the field is evolving and app evaluation frameworks (AEF)[12] and common glossaries[9] have been developed to overcome such limitations and increase methodological quality.

With this paper, we aim to provide current practical guidelines for researchers and practitioners in the field of e-mental health to cover the most important topics of the development, deployment, and evaluation of e-mental health assessments and interventions. The term *e-mental health* covers four types of digital services[13]: 1) information provision, 2) assessment

[1] see Smoktunowicz et al. (2020), for a "Consensus statement on the problem of terminology in psychological interventions using the internet or digital components"

for screening and monitoring, 3) intervention, and 4) social support. More specifically, this includes digital solutions in a comprehensive way, including mobile and web-based apps, digitally-delivered interactions with clients via e.g. video calls and chats, chatbots, and devices for assessing and monitoring health (e.g. wearables, smartwatches). Since the field is so dynamic, and constantly renews itself, we refrain from focusing on specific devices, data collection, analysis, or interaction methods, but aim to provide overarching and enduring recommendations.

METHOD

This is an expert consensus of the work of international researchers in the field of e-mental health aiming to promote methodological quality, evidence, and longer-term implementation of technical innovations in the healthcare system. For this purpose, the original author group from Germany investigated and contacted leading experts worldwide in the field of e-mental health based on Google Scholar profiles, groundbreaking publications and achievements, and personal recommendations. Thirty-six e-mental health experts were invited to contribute with their knowledge, provide an overview of the current state-of-the-art and give practical suggestios resulting in 25 authors and a think tank contributing actively (see Figure 1). The author's expertise covers multiple disciplines (psychologists, psychiatrists, computer scientists, industry) with different working areas (clinical studies, (tele-)psychotherapy, mental health state assessment, development and conducting of digital interventions in the field of mental health, app development, artificial intelligence) in children, adolescents, and adults around the globe. We sought diversity in terms of research seniority, culture, and gender.

For finding consensus on relevant recommendations and guidelines for clinicians and for researchers, an adapted, structured Delphi procedure in nine steps based on iterative feedback and co-reviewing by the authors was implemented[14], guided by LV, CS, and JL. Firstly, a list of the three most important objectives was discussed within the authors and agreed on: i) development, ii) study specifics, and iii) evaluation of e-mental health assessments and interventions. A total of 15 topics were brainstormed within the objectives (Terminology, Where to start, Content, Participatory Research, Target group, Suicidality, Data protection and data security, Artificial intelligence in assessment and intervention, Sensing and wearables, Drop-out rates and compliance, Efficacy evaluation, Ecological Momentary Assessment, Transfer into (clinical) practice, App evaluation frameworks). Thereafter, the topic "Drop-out rates and compliance" was removed as a separate chapter, and the section "Where to start" and "Terminology" as well as "Target group" and "Participatory research" were combined. Secondly, authors were grouped into teams due to their expertise and preference (2-4 for each section). All author teams were asked to include the latest literature and findings, clear recommendations respecting their topic, potentially helpful links for further literature recommendations, and a list of do's and don'ts for each topic (see Supplementary Material). After all authors delivered their first drafts, LV, CS, and JL reviewed the content and checked redundancies, and synthesised all parts into one piece on an online document, accessible and editable for all authors. Consequently, all participating authors were asked to review the whole manuscript and comment on each section regarding i) discrepancies, ii) agreement with their own experience, iii) literature recommendations, and iv) other comments. First-authors of each section finally discussed and/or integrated such comments with the support of CS, LV, and JL, who again developed a second clean version that was then handed over to more senior researchers in the field PC, EN, LN, and TR for a global check up and proof of coherence. Minor issues (typos, references) were resolved by the first and last authors, specific comments were fed back to the author teams and either discussed, integrated, or dismissed. To achieve a

final version and common “ground truth”, the last issues were syndicated, and all authors reviewed the again cleared manuscript and consented.

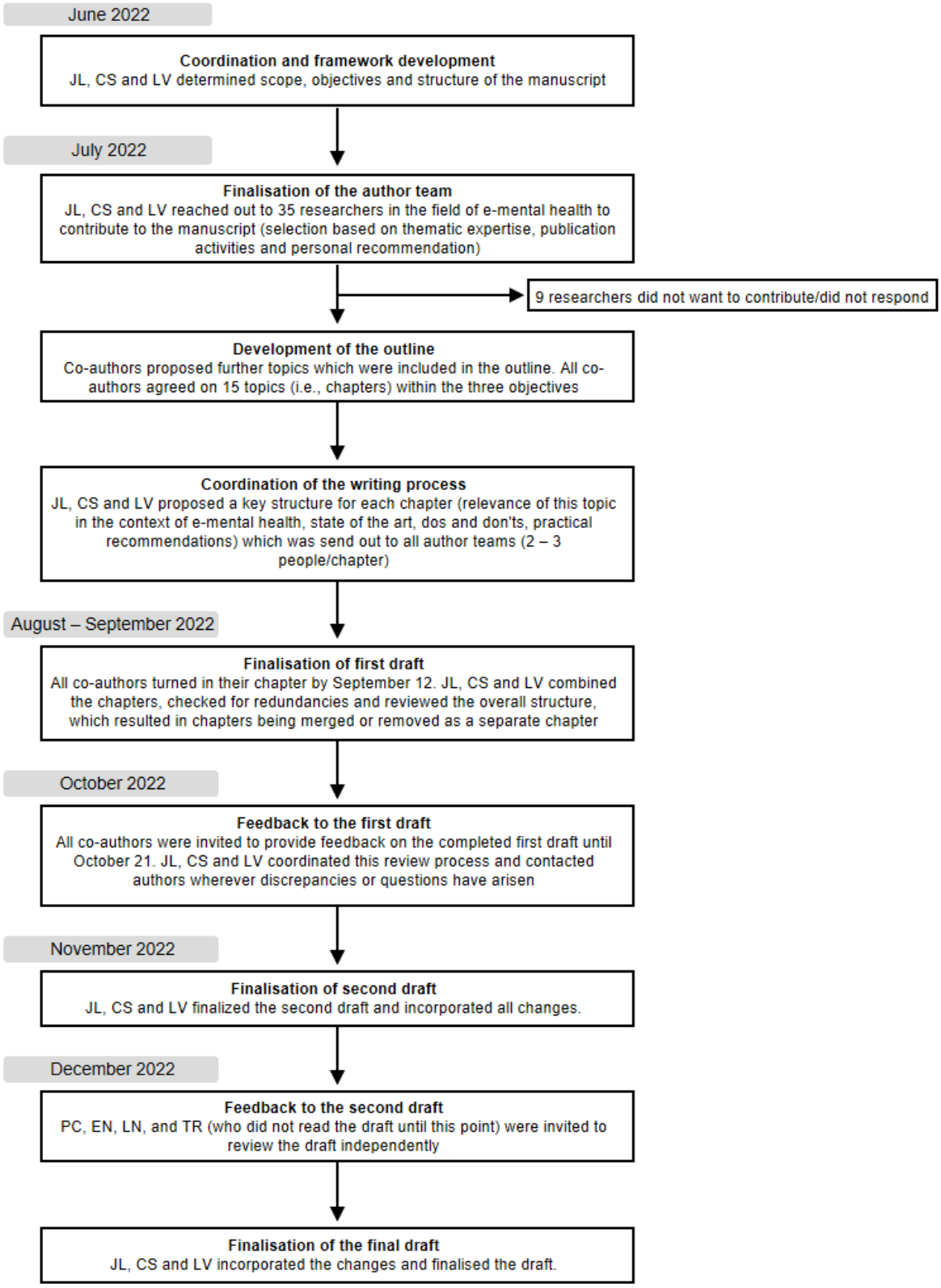

Figure 1. Flow diagram illustrating the manuscript creation process.

I. E-MENTAL HEALTH DEVELOPMENT

1. Where to start?

The implementation of any e-mental health project - assessment or/and intervention - is preceded by the fundamental decision about whether a digital approach is appropriate to address the specific research issue. Researchers need to identify the characteristics of the problem that allow for a digital operationalisation (i.e., multi-faceted, context-sensitive, time-sensitive) and the specificities of applying technology (i.e.. problem definition). Once it is established that a digital solution is the most appropriate approach, researchers can be clear about I) their **objectives, theory**, and **hypotheses**, which they aim to investigate. This may guide through several decisions that need to be taken throughout the process (see Figure 2). Furthermore, II) the specification of the main **target group** (i.e., demographics, mental disorder, cultural background) and the **target group involvement** (i.e., participatory research) is essential for following decisions, like III) the **extent** (e.g., self-guided, partly guided, blended counseling) and **nature** (e.g., on-demand, asynchronous, chat, video-based) of the delivered approach.

Digital technologies can be used to facilitate **communication** between practitioners and/or patients and can vary in their intensity of communication. Thus, the **level of interaction between users and providers** needs to be defined (e.g., guided by a research team for technical support, or therapists). Furthermore, content transfer may range from passively reading a text vs. clicking, and engaging more actively with the digital solution or with a coach/therapist. This, greatly depends on IV) the chosen **type of platform** that is used to deliver the e-mental health service (e.g., online and offline, browser or app). In this context, sensors can also be used (e.g., touch, motion, pulse, gaze) to provide direct feedback about physical and emotional responses. This decision also depends on budget and collaboration with (external, potentially commissioned) tech companies, self-made toolkit supplies for e-health studies, in-house IT support, and/or cooperation within a project with a technical partner.

For high-quality assessment and interventions, V) **best-practice** and **evidence-based components** should show the foundation of digital solutions. Furthermore, the definition of VI) the **technical development process**, including different disciplines, experiences, work cultures, and (project) aims should not be underestimated. Ideally, an agile, iterative process in a multidisciplinary team is set up to develop and transfer psychological content into an attractive digital solution. Especially for the implementation of gamification features, interactive content and delivery logic, an interdisciplinary shoulder-to-shoulder working culture is most promising. Together with the technical experts, VII) decisions about **data flow, data storage, access**, and **transparency** need to be taken and the following procedure clearly defined. Study participants should be well informed about such details and comfy their trust in academic e-mental health research (as a quality criterion, diverging from more commercially driven supplies). Following these steps, the VIII) **risk management** strategies and drop-out prevention may be defined. As a final step, the research team may determine IX) what study design best suits the **proof of objective and hypotheses**. Naturally, those defined steps interact, are dynamic and need to be reconsidered during the whole process. In addition, other specific frameworks and guidelines may support researchers and clinicians in their project planning decisions[15–20].

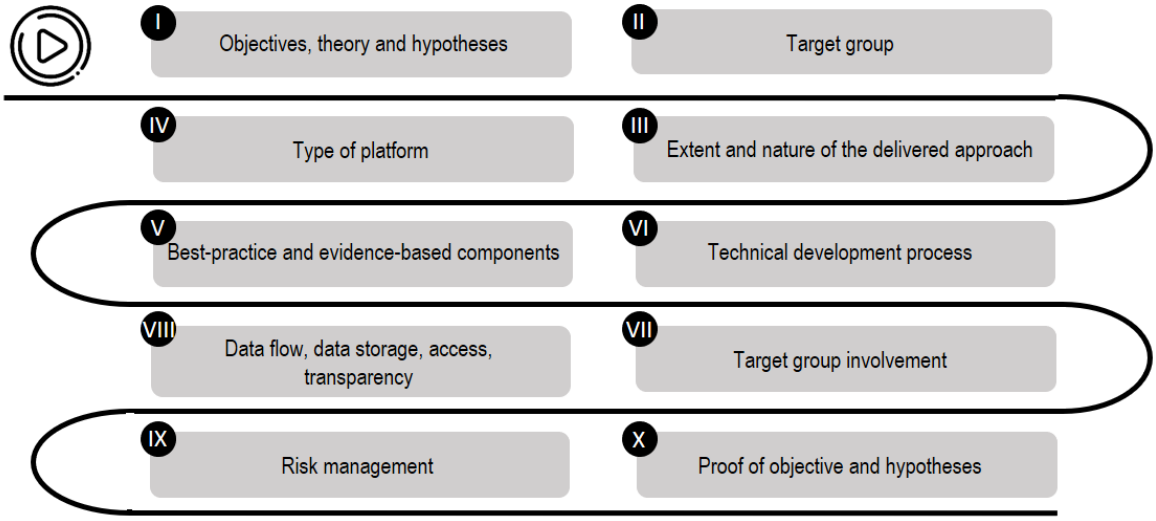

Figure 2. E-mental health study conceptualisation process

2. Intervention content development

The process of content development for a multicomponent e-mental health intervention is two-staged. First, researchers need to select psychological and psychotherapeutic strategies based on existing evidence or best-practice approaches for the selected target group and intervention aim. Second, the components of the intervention need to be transferred to the digital solution. This technical translation poses a range of pitfalls and therefore requires a highly iterative and dynamic research approach which should take place within a multidisciplinary team (e.g., mental health professionals, software engineers, design experts[6,21]).

A pragmatic approach comprises converting existing resources, such as applying psychological content from text-based manuals, exercises or questionnaires in agreement with the original authors. However, information displayed in digital solutions follows a rather different temporal and architectural structure and the user engages with the app with a different "user mindset" because app use occurs at varying times, with varying intensity, in varying contexts. To consider these peculiarities of the digital environment, a significant amount of time, financial costs, perspectives, and tests must be dedicated to the process of transforming specific components of traditional health interventions. More concretely, this means that each piece of content must be condensed to the core aims and elements that are to be conveyed through the digital solution. It is important that the structure (e.g., division into modules, sessions/lessons, and exercises), delivery logic (e.g., temporal availability of content) and complexity of content is always set against the background of the targeted group, and outcomes of the intervention. Once the crucial elements and user needs are determined, a user experience story may be developed.

Engaging elements may enhance a positive and reinforcing environment (e.g., text, audiovisual, prompts, quizzes, self-report questions, gamification features). Although forced guidance through an assessment or intervention may be needed to address the research objectives, flexibility and the personalisation of features (i.e., Just-in-Time Adaptive Interventions[22]) are likely to be beneficial to increase the attractiveness of an app-based or smart-phone intervention[23]. In general, the content should match the "look and feel" of the digital format (e.g., length of a video, amount of text displayed[6,24]). It is also necessary to consider which resources are realistically available to the development team and if it is possible to develop

new, customised multimedia elements. Finally, content development should be specifically focused on the target group.

3. User-centered design and participatory approaches

The implementation of user engagement participatory research within the development of e-health interventions is currently recognised as a way to increase the ease of use as well as the likelihood to fit the users' needs. It is therefore recommended to limit common problems like low uptake, high complexity, and poor fit to the user's needs. Participatory research actively involves end-users, healthcare professionals, and other stakeholders in all stages of the development and research process (including the formulation of the research question and goal, planning research design, selection of research methods and outcomes, interpretation of results, and dissemination) by taking into account their views, needs, expectations, and cultural background[25,26]. For a participatory approach, it is mandatory that end-users also participate in the decision-making processes[27].

In the field of e-health intervention development, user-centered design (UCD) has been established in recent years[28,29]. UCD represents a systematic, iterative process with three phases during development[30]. First, an initial investigation of the users' needs should be conducted (e.g., differentiating children, adolescents, adults and elderly users). The purpose of the first phase is to identify the needs of the target group, and to identify features and characteristics of the intervention that would be acceptable and preferred. For example, strategies such as personalisation, gamification, and including a social component have been identified as important for the users' engagement[31,32]. Focus groups or interviews with future users or individuals in their environment (e.g., therapists) and/or open-ended written survey questions are suitable methods for user needs assessments. Qualitative research methods (e.g., thematic analyses) are suitable for establishing UCD guidelines[33]. Secondly, a prototype with key features of the intervention should be created, which can be used in usability tests[30]. During the third step, usability tests, researchers observe potential users interacting with the prototype in a controlled environment, while they are simultaneously thinking aloud[34]. Researchers take notes about the participant's behaviours, comments, and issues, to uncover and adapt functional and design flaws[29,30]. This phase is a balancing act between drawing evidence-informed strategies and content from the literature and combining them with ways of delivering this information in an acceptable and engaging way. Continuing to engage with the target group at this stage ensures that when the product is finalised, the target group has been involved and has provided continual feedback and guidance throughout the process, maximising the likelihood that the final product will meet the needs of the users. It must be noted that UCD represents a preliminary stage of participative research as participation takes on a strictly consultative role and the project's decisions are still in the control of the researchers[35]. To achieve meaningful participation, it is necessary to involve end-users as early as possible in the research process and in all decision-making processes.

Focusing on the target group's specific needs is particularly important when it comes to digital interventions, with significant variability in the aspects of technology that will appeal to different groups of users[36]. Clinical observation shows less adherence when participants expressed a wide range of needs but the digital treatment addresses a single disorder[37]. When identifying the target group, specifics that should be considered include age, gender, cultural (racial and ethnic) background, delivery context, and delivery format. This information can guide the best ways to engage with the specific target groups at the outset of the project. Additional questions relate to the answer if it is recommended by the mental health professionals. In a UCD, all potential specificities must be explored together with the target group[38].

Once the specifics of the target group have been identified, the next step is to conduct an appropriate stakeholder engagement process with all parties involved in the delivery, dissemination, and implementation of the intervention, as well as the end-users. In addition, the examination of the usual consumer behaviour by the specific target group may be helpful, e.g., what kind of health apps are used, how often, and what features are more or less appealing.

II. STUDY SPECIFICS

4. Managing suicidality

E-mental health research is often conducted with participants recruited via the internet without any face-to-face contact throughout the entire research process. As a result, both researchers and institutional review boards express great uncertainty about how to manage participants who are experiencing severe mental health crises like suicidal thoughts or behaviour (STB)[39,40]. In common practice (not only in e-mental-health research), individuals with a history of suicidal behaviour or who affirm suicide-related questionnaire items (e.g., item nine of the PHQ-9) are often excluded from trials at baseline[40]. This practice, however, results in almost no increase in safety for participants, because it overlooks that suicidality often is a highly fluctuating symptom[41] and study participants may conceal their suicidal ideation in order to be admitted to the study[42]. Moreover, while there is an established association between suicidal ideation and previous suicidal attempts with subsequent suicidal behaviour, their practical predictive utility in differentiating individuals who are likely to exhibit suicidal behaviour from those who are not is limited[43]. Indeed, most people who die by suicide do not score in commonly used suicide risk assessments[44]. Thus, excluding participants who score on suicidality items primarily reduces the external validity of study results[45], which poses potential risks to users when these interventions are implemented in real-world care.

Given the impossibility of eliminating the risk of suicidality in e-mental-health research, we propose implementing the following measures to increase participant safety during the intervention, as it has been practiced in prior randomised controlled trials of digital interventions specifically designed for individuals with STB[46]. The assessment of STB should be expanded, including the use of specifically validated questionnaires[47]. At any point where patients may potentially report suicidality (e.g., in the intervention or questionnaires), it must be ensured that this is noticed by the study team. The study protocol should specify how to react to reports of STB, and these procedures should be trained and team members be supervised. This reaction can, but does not necessarily need to include a telephone or other contact by the study team. However, in case of a disclosed immediate and definite plan for suicide, the country-specific emergency services should be informed. Participants should be clear about these procedures as well as about the timeframe within which their entries will be seen by a member of the study team. We recommend documenting this in the informed consent. When STB is reported, detailed and visible information on support and contact services (e.g., national emergency numbers and 24-hour help lines) should be provided automatically including low-threshold click-to-call links. The use of other forms of treatment should not lead to an exclusion from the trial. Instead, individual crisis plans should be developed together with the participant. For studies with particularly vulnerable study samples, a collaboration with local emergency centres should be arranged in advance. In intervention trials for mental disorders, optional modules that specifically target STB should be available[46,48]. In general, help options should be equally available to all participants, irrespectively of their group allocation and the type of intervention[35].

5. Data protection and data security

Significant deficiencies in data protection and data security may inhibit e-mental health assessment and intervention studies[49,50]. The focus of data security is to prevent unwanted data loss and the unauthorised manipulation of data. The protection of personal data (e.g., patient contact details) is of uttermost importance in e-mental health applications.

In the development of an e-mental health offering, it must be anticipated that users may unintentionally reveal their access data, lose their devices, or use the devices for other (harmful) actions (e.g., children visiting adult websites). To counter these problems, tools can be installed on devices that lock access to other content. Preconfigured and password-protected study smartphones should be used. Two-factor authentication prevents mass registrations by fake users that can lead to poor data quality. In any case, users should be thoroughly informed about typical problems and dangers. This also applies to harmful software that the user captured unintentionally (e.g., keyloggers and spyware spy on sensitive data).

Further challenges include incorrect programming, which can enable unauthorised access to sensitive data. Therefore, a quality-assured software development process is essential[51]. If a manufactured app is used, the data should be stored in the healthcare institution's storage facilities rather than in the manufacturer's cloud. An external data hosting service provider should be certified. No data should be stored permanently on the device of the user, and a virus and trojan scanner should be installed. Immediate data transfer instead of data storage on the device as well as automated data backups could also ensure data quality. To prevent an attack where data traffic is intercepted, manipulated, or deleted, an end-to-end encryption (via TSL/SSL) should be used to transfer data. There should be brute-force attack protection built into the platform and all information in the database should be encrypted using a high-end algorithm with separate keys for each study.

The most effective measure is the pseudonymisation of sensitive data, which makes it worthless for unauthorised persons without any additional information[52]. The process of pseudonymisation and internal de-pseudonymisation of the data must take place in a separate system[52] and be considered even before the selection or development of an e-mental health system. Data protection and transparency are especially relevant for the use of artificial intelligence (AI) methods.

6. Artificial Intelligence in assessment and intervention

AI holds great promise for e-mental health, largely owing to the advances in affective computing. The latter includes the analysis, synthesis, and reaction to the affect and emotions of humans using the former. The last decade has seen major progress thanks to the rise of deep learning as an enabler in (generative) AI[53].

Likewise, great progress has been made in the recognition of emotion (e.g., in categories or dimensions such as arousal and valence), depression (e.g., in "dimensions" such as depression assessment questionnaires as the BDI-II or PHQ-9), or other mental disorders[54,55]. The means of assessment serve mostly audio (e.g., speech), video (e.g., facial expression, body posture, gait), text (written or spoken language), and physiology (e.g., via heart rate, skin conductance). A series of research competitions (e.g., AVEC[56]) have been benchmarking the progress of the community including tasks of the above from these modalities. Additionally, several reports exist on successful emotion and depression analysis from phone usage data, touch, and other information sources[57]. At the same time, readily available toolkits independent of the application domain and target tasks are sparsely available as "out-of-the-box" solutions. Usually, training these to match the target domain and target task is required. Also, robustness of real-world applications "in-the-wild" has increased notably over the last decade[58]. However, not all free-for-research and beyond solutions include state-of-the-art de-noising, target person

verification, or features such as subject adaptation. In addition, while such solutions often work largely independently of the subject, most of these tools are mostly geared towards a specific culture or language, or another context, due to the data they were trained upon. For practical solutions, this requires usually to re-train such tools or "engines" on the target data.

Emotion can also be synthesised with increasing realism by AI and recently deep learning approaches – often reaching human-level or close-to-human-level quality for speech and image or even language rendering. This led to effective virtual agents such as the "sensitive artificial listeners" that may be implemented in clinical practice for assessment and interventions. Again, platforms are available open source and free for research, but usually require some adaptation to the target task. Most notably, the AVEC challenge series had recently hosted the first ever "AI only" depression challenge, where interviews were conducted by an AI, and the recognition of depression severity was also conducted by AI reaching competitive results concerning human assessment considering the subjective nature of the task.

The recent past brought further breakthroughs in AI and particularly Deep Learning by the advent of transformer architectures, and diffusion approaches enabling a next generation of abilities in recognition of affect, and generation. This era is also coined by the "foundation models": These extensive data pre-trained models are marked i) by convergence, i.e., rather than training "your own model" from scratch, the trend is to use these models and fine-tune them to one's needs, which led to considerable improvements in a field, where data is continuously (too) scarce; and ii) by emergence. The latter is fascinating, as, while these models may not have been trained on tasks in affective computing or such relevant to e-mental health, they may show emergent skills in these stemming from the sheer "big" quantities of data they were trained upon. In Amin et al (2023), it is shown that the well-known ChatGPT (a general pre-trained transformer (GPT)) can predict suicidal risk at competitive performance "out-of-the-box" levels. This is without fine-tuning and training on the task, when compared to traditional and deep approaches fully trained on the task[59]. Similarly, Dall-E 2 - also based on GPT - can paint emotional faces from verbal descriptions - arguably also emergent behaviour from the perspective of affective computing. In short, we seemingly enter an era where e-mental health relevant skills can emerge in AI of the present and the future, which are big-data trained in a more general manner, such as foundation models. Such models could render even explicit training of tasks increasingly obsolete. In combination with the increasing power of generative AI ("GenAI"), interventions could be produced in a rich manner including questioning and chatty communication, potentially including the audiovisual rendering of artificial therapists, which are highly personalised and socio-emotionally empowered. Current foundation models such as GPT-4 or Metaverse as virtual space may be only a sneak preview of the oncoming power and abilities, which may help overcome the uncanny valley of such artificial therapists and help AI get to know patients better than any human depending on their data access. Accordingly, they might also soon be able to influence us in strange ways.

Potential dangers may relate to AI-driven chatbots or generative AI such as ChatGPT, which can be charismatic and appear emotionally involved due to expressing emotions (with emojis or an empathic language)[60]. This interaction may implicate an image of being a friend or human but if assumed would be highly unethical. Since individuals with mental illness are a vulnerable group, often longing for appreciation and insecurity in social contacts, great emphasis must be put on ethical guidelines. Bot-based interaction must be recognised as non-human to minimize the possibility of manipulation and harm or even dependence on the interaction with such AI - potentially at the cost of human relationships[61]. Furthermore, such AI may find its ways of behaviour, which may be even more persuasive and change the human-to-human behaviour of

such interacting with it in the long run. Asking participants to use sensing and wearable data collection tools can often provide supplementary data to support AI research methods.

7. Sensing and wearables

Historically, diagnosing mental health conditions has relied on thoroughly validated self-report questionnaires. While questionnaire-based assessments are an indispensable source of information in this context, they are purely based on introspection, can lack vital information that is systematically neglected by the patient (e.g., due to self-other knowledge asymmetry[62]), are temporally constrained (i.e., one-time, infrequent assessments), limited in granularity (i.e., in terms of a selection of questions in the anamnesis), and suffer from floor and ceiling effects (i.e., lack sensitivity to change at their scale's extremes). Foremost, it is becoming increasingly apparent that patients are likely to be not able to self-report the fine-grained and complex patterns of behaviours in various situations of daily life that characterise their physical and psychological traits, states, and changes in these.

The ongoing evolution in *mobile sensing* and *mobile computing and communication technologies* ameliorates this situation. More and more sophisticated and accurate sensors in consumer electronics (e.g., smartphones or wearables) allow for the unobtrusive and automated collection of high-frequency, objective, longitudinal data on human behaviours, states, and environmental conditions[63,64]. Figure 3 provides an overview of the variety of data that off-the-shelf consumer electronics sensors can provide.

Figure 3. Overview of mobile sensors embedded in consumer electronics and variables they provide[65]

On a growing scale, mobile sensing data is increasingly being used throughout the health and behavioural sciences to understand behavioural aspects of mental health through digital biomarkers[66–68] to detect health conditions and deterioration[69,70] and improve conditions through behavioural interventions[71,72].

While mobile sensing is becoming increasingly established as a method in mental health research, its standardisation is challenging due to rapid and frequent changes in hardware, operating systems, and ethical and legal frameworks, amongst others[12,73]. Participants should be aware of often liberal data storage and access policies of companies. While this circumstance has acted as a roadblock in the past, the main mobile operating systems have started to develop standardised so-called application programming interfaces (APIs) for researchers to access and use in empirical studies (e.g., Android Health Connect[2], Apple SensorKit[3] or HealthKit[4]).

However, the most innovative methods can be useless if they miss the mark. While offering specific new opportunities, e-mental health interventions need to be evaluated properly.

III. EVALUATION

8. Efficacy evaluation, RCTs, and other methods

There is no shortage of available e-mental health interventions, most of which are not well-evaluated[74]. However, despite the young age of the field, high-quality evidence is needed from the start, as unreliable results can stick around in a classic canon of literature[75] and lead to low quality of developments, or even harm the patients. This section offers recommendations and ideas for how to produce this high-quality evidence. While there are some unique ways to evaluate e-mental health interventions, which will be addressed below, a good starting point for an evaluation study are the same principles that apply to classic interventions: Besides observational or case studies, the gold standard to evaluate (mental) health interventions are randomised controlled trials (RCT). First meta-analyses of e-mental health intervention RCTs show promising effects, even when compared to face-to-face treatments, but also that primary studies have been focussing on a small range of diagnoses and age groups[76]. A high variance in types of control groups and interventions further reduces the amount of knowledge that can be gained from meta-analyses. Therefore, the field would benefit from further RCTs addressing these issues.

When setting up and selecting variables for an evaluation study of an e-mental health intervention, past studies of classical interventions can serve as an example. Researchers and practitioners still need to investigate any potential adverse treatment effects[77] and the importance of mediators and moderators of treatment effects that apply in face-to-face settings (i.e., symptom severity, self-efficacy, motivation, age or amount of therapist involvement). Special attention should be paid to therapist effects,which robustly explain a relevant amount of variance in classical treatment outcomes[78]. For the evaluation of e-mental health interventions the type of the application (stand-alone, prescribed after seeing a professional, continued blended care) can influence which therapist effects are present. There might be none if there is no therapist involved, they might be similar to classical mental care, or they might be even stronger, e.g., when negative biases of a professional towards digital solutaions are present. Studies should aim for an extensive and diverse pools of therapists, also because estimates of the therapist-level random slope suffer from more bias when there are very few therapists in a study[79].

Going beyond these traditional evaluation standards, evaluations of e-mental health interventions offer exciting new possibilities: The underlying technological infrastructure has the potential to extend the classical outcome-oriented designs and measures as it becomes more

[2] https://android-developers.googleblog.com/2022/05/introducing-health-connect.html

[3] https://developer.apple.com/documentation/sensorkit

[4] https://developer.apple.com/documentation/healthkit

achievable to measure various *process variables*. These can focus on psychological content, such as therapeutic relationships (e.g., rupture-repair[80]), sudden gains/losses[81] or personalised items and networks[82,83]. Time series data on an individual level will allow new hypotheses to be answered. Also, by using shifting time windows, one can produce a meta-time series of e.g. dynamic variance or critical fluctuations and use their change as an outcome variable[81,84,85]. Another possibility is to evaluate individuals' network parameters (e.g., networks of symptoms) and their change over time or recurrence plot quantification[86,87]. In short, the type and amount of data from e-mental health studies can change the classical approach of *aggregating first (across participants) and analyse second* to *analyse first (on the individual level) and aggregate second*. Therefore, e-mental health studies have the huge potential to expand the concept of traditional RCTs. Going beyond RCTs, further methodological approaches (e.g., A/B testing, trials of principles) can be used to test small differences within an intervention or to test the efficacy of a general principle of an electronic solution (e.g., self-monitoring). These approaches of agile science might contribute to the reduction of the time discrepancies between technical development and evaluation results[21] which is especially important when working with fast-changing technologies. As a specific option for evaluation, Ecological Momentary Assessment (EMA) will be discussed in the next section.

9. Ecological Momentary Assessment

EMA (synonyms: ambulatory assessment, experience sampling method, real-time data capture) encompasses a range of methods that involve repeated assessments of individuals' dynamical experiences and behaviours in their natural habitat, thereby increasing both ecological validity and generalizability, while minimising recall biases[88,89]. This method can be used in various stages of the therapeutic process (e.g., diagnostic process, tracking the course of symptoms during treatment and, transfer of therapeutic effects thereafter).

EMA offers the possibility to combine subjective assessments with further methods (e.g., psychophysiological and physical activity assessments)[88]. EMA also allows for integrating continuous mobile sensing (i.e., digital phenotyping[90]) to predict critical phases[91] and to improve the timing of EMA inquiries[88]. By providing a detailed picture of mental state and functioning, EMA promises to be more sensitive to capturing change and, thereby, improving the assessment of the therapeutic effects of interventions[92]. One of the most promising avenues of EMA is the opportunity to extend treatment beyond the clinical setting into real life using e-mental health applications[93].

When setting up a study, the following aspects are very important: There are various sampling designs (i.e., time-based, event-based, combined sampling schemes). Choose the one that fits your research question. Carefully balance the length of the questionnaire presented at each assessment, the number of assessments per day, and the assessment epoch to ensure high compliance rates[94]. Also, allow participants to delay or actively decline alarms. Choose an adequate time frame for the questions. Whereas questions referring to the present moment minimise retrospective bias, those with a specific time interval enhance representativity. When deciding on the order, group items with the same timeframes, and ask transitory constructs (e.g., emotions) first, questions that are not likely influenced by preceding questions (e.g., context) at the end. If you must develop new items, use two, or better three per construct, to be able to determine the items' reliability[95]. A crucial point is that the sampling strategy must fit the temporal dynamics of the underlying process; otherwise, results can be misleading[96].

Carefully determine the length of the EMA period that is needed to answer the research questions. However, balancing the lengths is key to ensuring participants' compliance[94,97]. Meta-analytic results revealed higher compliance rates in studies offering monetary incentives

compared to other or no incentives[94]. Moreover, linking the incentives to a certain degree of compliance might reduce dropouts during the assessment period[97].

10. **Transfer into (clinical) practice**

To make e-health interventions feasible for real-world settings, the following criteria should be considered: (1) research should integrate follow-up measurements to assess long-term usage since there is a lack of meta-analysis on long-term benefits of mental health apps as the handling of follow-up measurements and dropouts is inconsistent[76,98]. Indeed, reviews showed that too few studies used (long-term) follow-up measurements and many showed huge dropout rates of 47%[99,100]. (2) Researchers, developers and practitioners should consider relevant factors to improve adherence to digital health interventions in real-world contexts[101]. When looking into real-life settings, Fleming and colleagues[100] found in over 10,000 digital mental health apps only 11 peer-reviewed publications analysed uptake and usage data in such real-life settings. The completion rate was between 44-99% in RCTs but dropped to 1-28% when looking at real-world usage. Furthermore, new (machine learning) approaches showed that a distinction into user subtypes and, therefore personalisation of interventions could lessen the effects of interventions[102]. Thus, researchers and developers should consider relevant factors to improve adherence to digital health interventions in real-world contexts: (3) Integrate mood monitoring, feedback and human/automated support to lower dropout rates[103]. For example, dropout rates decreased by 46% when therapeutic support was provided and even minimal care with only administrative support resulted in a meaningful decline in dropout rates[104]. Further, it has been shown that when specific data of EMA is fed back to clients regularly, the number of missing EMA data is low (<10%) and reduces over time[85]. Digital health is a global challenge, but the implementation of digital health interventions is based on complex national and local economic and political processes. (4) Hence, when conceptualising and evaluating the implementation process of e-mental health interventions researchers and practitioners should always consider the integration of all relevant stakeholders that will be involved in the final roll-out of the digital interventions, such as lived experience users and beneficiaries, companies, health insurance, or other political institutions and decision-makers. We argue that for each digital intervention a unique approach for its roll-out should be considered and developed along with its scientific evaluation. Target groups, clinical scope (prevention or intervention), business models, funding strategies, long-term technical maintenance, requirements for quality management, regularity frameworks, data safety, market access, and reimbursement schemes are only some examples to be considered. The exploitation of evidence-based interventions may further benefit significantly from the flexibility, variety of resources, and agile methods of industrial partners. Even where the process is successful, any on-going quality control in clinical practice is substantial and very challenging in a dynamic field of tech industries. Furthermore, potential side effects tend to be underestimated, leading to a broad supply of unapproved interventions.

11. **App evaluation frameworks**

As the number and diversity of e-mental health solutions increases, so does the need to evaluate which are most effective and safe. While regulatory bodies are beginning to approach the regulation of primarily mobile and web-based apps but also other sorts of digitally delivered interventions, most efforts remain nascent[105,106]. This means clinicians and patients must rely on tools like app evaluation frameworks (AEF) to help them make more informed decisions. While there are also an increasing number of AEF, there are differences in their approaches with some providing scales vs. ratings, subjective vs. objective metrics, and others information vs. databases. Each approach has a unique value depending on the use case and clinical needs.

Perhaps the largest category of app evaluation is scales or frameworks that provide guidance and information on how to consider an app. For example, the American Psychiatric

Association's app evaluator framework[107] provides a four-step process with corresponding questions about privacy, efficacy, engagement, and clinical utility. While this framework does not provide scores or ratings, there are other frameworks such as the Mobile Application Rating Scale (MARS)[108] that do. Often these rating systems require training before they can be properly used. Ramos et al.[109] reviewed popular frameworks through the lens of diversity, equity, and inclusion and found that only 58% included related metrics which offer a target for future efforts and evaluation criteria whether subjective or objective.

A related consideration in app evaluation is the use of subjective vs. objective metrics. For example, questions about the aesthetics or usability are inherently subjective and will vary between users. Examples of objective metrics may include videos or music in an app. Each approach has merits and subjective evaluations, often in the form of user or expert reviews that can provide rich contextual information about an app. However, it can be challenging to keep these reviews updated and current in the rapid-paced world of apps[110]. Objective metrics may not offer such context but often provide easier-to-update approaches that may have higher inter-rater reliability by their very nature. One example of such an approach is the Mobile App Index and Navigation Database (MIND, mindapps.org) which rates apps across 105 criteria that are derived from largely objective criteria[111].

A further consideration is how users can engage with any AEF, whether it offers subjective or objective metrics, frameworks or ratings. Some approaches like Psyberguide, MIND, and UK's National Health Service Apps Library maintain websites that users can search while others provide only the rating scale or related educational material. The impact of either approach remains unstudied although recent research suggests that digital literacy and health app awareness are important related factors for app use[112]. Some newer approaches like the adapted Mobile Application Rating Scale (A-MARS) have been proposed with the authors suggesting the need for concomitant support from a coach or digital navigator[113].

DISCUSSION

The COVID-19 pandemic boosted the supply of digitally delivered assessments and treatments, along with the promise of increased availability of digital, low-threshold treatment for mental illness worldwide. However, e-mental health research and practice is still in an embryonal stage of development and evidence-base. As the first of its kind, this expert consensus provides a comprehensive essence of scientific knowledge and practical recommendations for both practitioners and researchers (see Do's and Don'ts in Supplementary Material).

In summary, when researchers agree on using a digital approach, they should define the development and evaluation process carefully, guided by their main objective and theory. The technical transformation of psychological content requires a transdisciplinary, participative and highly iterative research process which swallows up a range of resources that need to be estimated when planning the project. Data protection and the inclusion of vulnerable groups pose challenges to the successful implementation and should be given special consideration while adhering to current standards during the development and implementation by a user-centered approach. AI holds great promises for e-mental health, largely owing to the advances in affective computing. Mobile sensing and EMA have a huge potential to enable accurate assessments of individuals' daily life states and behaviours, which can be used for diagnostics and evaluation of interventions. RCTs are one element of an evaluation strategy for e-mental health, but should expand their focus to a wider range of populations, control groups and investigation of process variables and individual data patterns. AEF offer useful heuristics to identify apps of interest, and to share data on privacy, efficacy, engagement, and clinical

integration but cannot replace clinical judgment. In order to use e-mental health interventions in the context of prevention and intervention, it should be feasible for real world settings.

Despite all technical innovations and novel features, one should not neglect the final goal of all attempts: health that is defined as "the ability to adapt and self manage in the face of social, physical, and emotional challenges"[114] enabling an individual to work, have relationships, and express oneself in a society. Well-executed e-mental health assessments and interventions have the potential to be meaningful to individuals and their care teams. Rather than replacing health professionals, digital technologies have a potential to support the human therapeutic process in a scalable format (e.g., by providing interactive psychoeducation and monitoring material). With this expert consensus, we aim to provide guidance on best practice when preventing or improving the state of mental illness using e-mental health interventions. The target group with its needs and wishes should be placed in the foreground to achieve this. Of paramount importance are high ethical standards, transparency, respect for patients' rights, data protection, the special consideration of vulnerable groups, and the explicit clarification of any non-human interactions. In the dynamic field, it is also necessary to rethink the classical statistical methods of development and evaluation of digital tools in order to not to lag behind the market in practice. It may be advisable to include flexible, iterative, built-in behavioural digital assessments and process monitoring and to collaborate with companies to provide exploitation and implementation with a viable business model, as digital intervention's availability and sustainable quality of digital intervention depend on it.

We further emphasize the need for feasibility and long-lasting usage based on long-term follow-up measurements, evaluation in real-world settings, considering factors that improve adherence, and integration of relevant stakeholders in the conceptualisation, implementation, exploitation, and roll-out process of the digital intervention as well as the integration of comprehensive process quality evaluation based on recognised international frameworks. Suicidality should not be an exclusion criteria, but it should be included once an adequate monitoring policy is established. Another groundbreaking development is generative AI outcomes such as GPT-4 or Metaverse, as virtual space may be only a sneak preview of the oncoming power and abilities supporting mental health aid. However, such AI, if not governed, might also soon have the ability to influence the mental health domain in unknown ways. Ethical considerations must be prioritised shielding potential harm and manipulation, especially in vulnerable groups such as individuals with mental illness.

To support the development and usage of high-quality e-mental health offers, the research field must be expanded, especially regarding long-term efficacy analysis, adherence, patient satisfaction and improved uptake, cost-benefit analysis and a facilitated access for clinicians and patients to evidence-based interventions within the routine healthcare. We claim a proof of efficacy as a prerogative of transfer into clinical practice, since side effects of e-mental health intervention have not yet been studied comprisingly and may be underestimated.

This expert consensus is unsystematic, primarily based on the subjective experience of a selective group of clinical and scientific experts, mostly from Europe, the U.S., and Australia. This is noteworthy, since a key advantage of e-mental health is providing low-threshold access to mental health services in particular in more rural regions with a limited supply of health care services. Given the increasing number of smartphone users worldwide and the expanding reach of mental health apps within high-income countries[115], providing early scalable psychoeducation and online training in a stadium of mild symptoms or for early recognition, digital assessment, and intervention methods are especially promising in preventing more severe courses with low costs[116]. In addition, the geographical range and duration of treatment

can be expanded e.g., by using video calls and chats to stabilize clients through follow-up sessions, preventing relapse, and providing care at a low cost. Moreover, cost-effectiveness studies are scarce and especially neglect low-income countries where e-mental health services may be particularly beneficial[116,117].

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Author contributions

JL, CS and LV conceptualised the study and supervised the writing process. JL, LV and CS wrote the first draft including Introduction, Method and Discussion. The chapters were written in the following writing groups: *Where to start:* KH, IB, JL, CS; *Intervention content development*: CS, JL; *User-centered design and participatory approaches*: LV, LBS, AWS, JL; *Managing suicidality,* LBS, KH, *Data protection and data security:* HL, IB, AC; *Artificial Intelligence in assessment and intervention:* BS, JL; *Sensing and wearables:* KW, YT, RS, CST; *Efficacy evaluation, RCTs and other methods:* AO, BA, STT, AC; *Ecological Momentary Assessment*: PSS, MF; *Transfer into (clinical) practice*: SW, BA, EM, STT; *App evaluation frameworks*, JT. All authors commented on the first and final draft. PC, TJR, AN and NE reviewed the final version particularly. All authors share responsibility for the final version of the manuscript.

Competing interests

PC has received speaker fees from Angelini Pharma, Lundbeck and Koa Health within the past three years. JT is a scientific advisor for precision mental wellness. LBS reported receiving personal fees from Psychotherapy Training Insitutes, Health Insurances and Clinic Providers in the context of e-mental-health but outside the submitted work. All other authors have no interest no declare.

Supplementary Material

Manuscript: How to e-mental health: A guideline for researchers and practitioners using digital technology in the context of mental health

Table S1. Do's and don'ts researchers should consider when implementing an e-mental health intervention and/or assessment.

I. DEVELOPMENT	
Where to start?	
 ● Examine the context of use and identify the digital specifics to solve the problem ● Involve the target group (and other important stakeholders) in the development of the application from the beginning and tailor it to it/them (i.e., selection of the features) ● Get expert advice on data protection and privacy while writing the funding proposal ● Obtain quotations from several external IT partners at an early stage in order to structure the budget accordingly ● Check similar solutions in the field beforehand and identify well-evidence based open access material (e.g., no-code software development) ● Consider budget for the support of the digital solution after completion (e.g., installing updates, fixing bugs)	 ● Do not assume a priori that a digital health solution is the most appropriate approach for every problem/context of use, but explore if this approach is best (or at least better than existing ones) ● Avoid developing the application purely from a researchers point of view (potential driver for low user engagement) ● Avoid having a static mindset and a finished technical solution in your mind, but engage in an iterative process (guided by your objectives and the target group) ● Do not discard your project timeline too easily but try to use resources proactively and continuously monitor the project to anticipate delays
Intervention content development	
 ● Plan sufficient resources (i.e., financial, time, personnel) for the technical translation of therapeutic content when planning the project ● Put together a transdisciplinary team (e.g. mental health professionals, software engineers, design experts) and plan time for the development of a mutual understanding and finding a common ground ● Define features or content which allow for personalization of the e-mental health intervention (i.e., just-in-time adaptive interventions, self-monitoring tools, notification) ● Ensure that different multimedia elements are implemented and that there is some variety across the intervention (i.e., gamification)	 ● Do not take elements of existing static, text-based psychotherapeutic manuals and implement it one-to-one without considering the characteristics of the digital environment and the target group ● Avoid following a linear development process, but rather an agile iterative research process ● Do not adopt a 'one design fits all' approach ● Avoid modifying the core principles of the evidence-based intervention, but identify possibilities to transfer them into the digital environment
User-centered design and participatory approaches	
 ● Plan sufficient financial and time resources for users' inclusion throughout the study/development ● Define the target groups as precisely as possible ● Include the environment of your target group (e.g., professionals, therapists, relatives) ● Involve the target group as early as possible	 ● Do not overlook that various subgroups are represented within focus group/selected advisory group/stakeholder (i.e., equal gender, ethnic minorities, age) ● Avoid neglecting awareness of who is conducting the interviews (i.e., should they be part of the development/research team and final product or do they face the risk of being biased?)

• Involve target users/ stakeholders also in decision-making processes • Identify key needs and preferences of specific target groups • Identify access routes and potential barriers of your target group • Conduct focus groups and qualitative interviews • Include advisory board with all needed stakeholders	• Do not presume what the target group might want and do not confirm assumptions on ready-made interventions • Avoid conducting few focus groups only and do not present only finalised material

II. STUDY SPECIFICS	
Managing Suicidality	
• Incorporate separate modules with specific content for people with suicidal ideation (i.e., emergency contact details) • Routinely include a measure of suicidal thoughts and behaviours • Assist participants with moderate to severe suicidal ideation to develop an individual crisis plan • Train and supervise team members who provide guidance to participants to ensure qualified patient support and the well-being of the staff • Rigorously assess reasons for dropout (i.e., include third persons to follow-up on participants who cannot be reached)	• Avoid excluding participants with suicidal ideation from trials • Do not exclude suicide-related items from other scales (e.g., PHQ-8). • Do not offer the intervention group better crisis support than the control group • Do not prohibit co-interventions for people with suicidal thoughts or behaviours • Do not start trials without a pre-specified crisis support plan • Do not obtain contact information of participants and/or their general practitioners, although the study design would allow this
Data protection and data security	
• Pseudonymizise sensitive data wherever possible • Consider a two-factor-authentification if appropriate • Let the app be developed under your control, avoid commercial manufacturer apps if possible • Demand a quality-assured software development process (i.e., thorough analysis of requirements, detailed specification of data flows, data processing and data storage, precise test strategy) • Involve your data protection officer in the project at an early stage and establish in-depth technical know-how in your own institution • Use open source libraries in software development if possible • Use a research database developed for this purpose which is separated from other institutional information systems • Educate the users about dangers	• Do not upload data in the vendor's public cloud or in an unknown destination • Do not save sensitive data on the smartphone permanently • Do not rely on external IT partners only • Do not keep the de-pseudonymization list in the same database as the e-mental data • Avoid commercial manufacturer apps if possible • Do not start without any risk assessment • Do not neglect the national protection laws
Artificial intelligence in assessment and intervention	
• Recognise emotions in different categories, modalities and sources (i.e., clearly define input and output vocabulary/data model)	• Do not neglect validation and robustness test in the target population (including e.g. culture, language, age)

● Train toolkits or "engines" on target data ● Use open source AI tools (algorithms, syntax) adapted to the target task ● Validate AI for bias in your population (e.g., use model evaluation cards or similar to check for fairness issues and others)	● Do not use features of self-fulfilling predictions
Sensing and wearables	
● Define device type (unisensory vs. multi-sensory, smartphone vs. wearable, operating system: e.g., iOS vs. Android) ● If possible, try to incorporate the user's usual devices (smartphone and wearable) ● Consider evidence for the device's reliability/validity and contact manufacturer in case of evidence is not clear ● Wearing wearables should be enjoyable, even fashionable ● Decide whether to use in-house vs. outsourced mobile-sensing platform ● Assess if you have the raw data or features ● Assess ethics of data capture ● Consider details of the back-end (e.g., reliability, geographical location, security) ● Chose a sufficient time interval for piloting and plan time to improve things after the piloting ● Prepare communication channels with participants in case of data loss/technical errors ● Assure enough time to acquire ethical study approval(s) and to design data privacy concepts in advance ● Transparently document your device choice and study setup (e.g., device firmware /software version; sources of potential biases, including study-unrelated behaviours that might influence the collected data quality; nested structure of measurements such as within days/weeks) ● Have a procedure of "sensing device hard reset" to return to default configuration ● Report the process of the data access in studies (raw data, processed data via dedicated webs, mobile platforms, APIs) and clarify the details with the manufacturer if necessary ● Watch out for dependencies: behavioural interventions (e.g., drug trials) may affect device performance due to the dependency of device accuracy on features that will change as a result of the manipulation (e.g., accelerometer, heart rate and its variability, temperature) used by these devices ● Adhere to established reporting guidelines depending on your study design (following the	● Do not assume that devices are always sufficiently charged (i.e., assure no less than a day of battery lifetime) and 'always on'/connected ● Do not assume manual synchronisation (if required) more than once a day ● Do not use devices that are potentially unsafe (e.g., invoking an allergy), hard to use or malfunctioning (require a specific interaction to function accurately) ● Do not use devices that require participants to use large screens/laptops or PCs ● Do not use devices which costs are disproportionate with the usual devices the population is using ● If wearables: do not use obstructive or stigmatising devices ● If wearables: do not use devices that are not waterproof ● Avoid developing new software and use existing frameworks whenever possible ● Do not outsource it to locations where privacy/security laws and practices are different (EU vs. USA vs. China) ● Do not assume the data is synchronising without errors ● Avoid convenience sampling of a pilot population unrelated to the intended target population (e.g., students vs seniors) ● Do not involve team members without adequate ethical training ● If possible, avoid accepting device software updates along study duration (unless the security may be compromised) ● Avoid using pre-defined data processing pipelines / algorithms that are poorly documented ● Avoid overwhelming the study participants with large selections of own raw data presented to them

EQUATOR and/or STROBE guidelines for observational studies and for diagnostic/prognostic studies: STARD and TRIPOD) ● Conduct and report reliability and validation analysis (e.g., Bland-Altman analysis if multiple devices are used simultaneously; nomological net analysis to check construct validity) ● Share early your algorithms for data processing and algorithm design	

III. EVALUATION	
Efficacy evaluation, RCTs and other methods	
● Especially in the early stages of development, use different forms of evaluation before moving on to an RCT, including qualitative analyses, such as focus groups with target groups or short interventional studies ● Before you begin an RCT, preregister your study, including all planned measurements; this avoids non-significant studies to vanish ● Think about how to measure processes and to go beyond RCTs when evaluating your intervention ● If you are using high-frequency assessments (e.g. EMA), consider how this might influence the effects of the intervention ● Consider different study populations and control groups and also blended designs including elements of e-mental health and traditional face-to-face elements	● Do not include variables in your study without a clear theoretical rationale for why these variables are important for the success of the intervention or as control variables ● Do not just publish the measures for which you have obtained significant results in favour of your intervention while not reporting other measures that failed to produce significant results ● Do not confuse correlation with causality ● Do not assume that the effects of moderators and mediators in traditional settings transfer automatically to an e-mental health setting; do not automatically exclude these variables
Ecological Momentary Assessment (EMA)	
● Choose an adequate sampling design (i.e., time-based, event-based, combined sampling schemes) ● Balance the lengths (i.e., number of questions at each assessment, number of assessments per day, and the assessment epoch) ● Use automatic repeated prompts/alarms and allow participants to delay alarms ● Determine the order of items considering the different timeframes of items (e.g., “right now” or ”since the last prompt”) ● Use items with good psychometric properties. In EMA, Mc Donald´s omega is the currently most often used measure of reliability. ● Consider the temporal dynamics: make sure that the sampling rate matches the temporal dynamics of the underlying target process. For example, a sampling rate that is too infrequent might miss the dynamics of interest, whereas a sampling rate that is too frequent to accurately assess the target process poses unnecessary burden on the participants	● Do not overdo the assessments but carefully determine the length of the EMA period needed to answer the research questions ● Do not be a miser. Offering monetary incentives seems to positively affect adherence rates

Transfer into (clinical) practice	
● Assess the long-term usage and feasibility of digital interventions ● Evaluate the implementation of the digital intervention in real-world settings ● Integrate intervention uptake, ongoing use and impact when assessing in real-world settings ● Use proven factors to improve adherence, e.g. mood monitoring or human support ● Integrate recognised international frameworks to identify relevant process evaluative indicators (acceptance, liability, functionality) ● Consider all relevant stakeholders in the conceptualization and evaluation process ● Develop a unique roll-out strategy and consider national/regional requirements such as regulatory frameworks, data safety, business models, long term technical maintenance, funding, market fit etc.	● Avoid efficacy studies without the consideration of process evaluation and a unique roll-out strategy ● Do not ignore relevant stakeholders in the public health system ● Do not assume that scientific evidence automatically leads to market acceptance
App evaluation frameworks	
● Ensure recommendations are up to date ● Assess assumptions and cultural bias in some recommendations, e.g., such as those that score “ease of use” ● Verify through your own testing that app recommendations appear accurate and in line with the needs of your populations ● Assess for any bias in app recommendation systems	● Do not assume app recommendations have taken into account cultural needs of your population ● Do not ignore patient preferences and needs in light of any app recommendation ● Avoid offering patients lists of ‘top’ apps without plans to discuss and/or incorporate into treatment

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Chapter 6 | General Discussion

Existing literature suggests that cognitive and emotional processes underlie health behaviors and thus influence weight (loss) management. Therefore, more and more assessment and intervention approaches in the treatment of overweight and obesity address and modify these psychological aspects. Digital health solutions such as mHealth offer a promising approach to assess an individual's health behavior (e.g., eating behavior, physical activity), emotional or cognitive processes, and to deliver psychological interventions. However, there is a lack of knowledge about the long-term effectiveness of these interventions and adherence to mHealth interventions is generally low. Individualized approaches are thought to increase engagement and thus the effectiveness of mHealth interventions. In the context of overweight and obesity treatment, gender-sensitive individualization is hypothesized to be beneficial as it takes into account the needs of male and female users.

Against this background, the overall aim of this dissertation was to provide a better understanding of individualized and psychological mHealth solutions implemented in assessment and intervention research for individuals with overweight and obesity. To this end, this thesis synthesizes the empirical findings of four original studies that examine the development and evaluation of digital assessment and intervention approaches. The four original studies that form the core of this dissertation have attempted to broaden the understanding of how mHealth assessment and intervention solutions in the context of overweight and obesity should be developed, implemented, and evaluated. In the future, this may help individuals with overweight and obesity to address and modify the underlying psychological aspects and successfully change health behavior in the long term.

Study 1 examined the bi-directional association between a health behavior (i.e., physical activity) and core affect in individuals with overweight and obesity using EMA. The development, acceptability, and use of the gender-sensitive psychological mHealth intervention I-GENDO were described (Study 2) as well as the evaluation of this novel intervention (Study 3). In addition, Study 4 proposed a guideline for practitioners and researchers on how to develop, implement and evaluate digital solutions in the context of mental health. The results of the four original studies are discussed below to address the research questions proposed in Chapter 1.5. Finally, the strengths and limitations of this dissertation are reviewed, and research and clinical implications are considered.

6.1 Research Question 1: Assessment of a Bi-Directional Association Between Core Affect and Physical Activity

Is there a bi-directional association between core affect (i.e., valence, energetic arousal, and calmness) and physical activity levels change in individuals with overweight and obesity at the within-person and between-person level?

The EMA study presented in Chapter 2 examined the bi-directional association between self-reported levels of valence, energetic arousal and calmness and device-measured physical activity in individuals with overweight and obesity (n = 157, BMI: 32.99±3.87 kg/m^2). The results indicate that there is a meaningful reciprocal relationship between ratings of energetic arousal and physical activity (positive association) and calmness and physical activity (negative association) at the within-person level. In answer to Research Question 1, we found that when individuals engaged in more physical activity in the 15 minutes prior to an affect assessment, they felt more energized (energetic arousal) and agitated (calmness). Subsequently, feeling more energized and agitated predicted higher levels of physical activity in the 15 minutes following the affect assessment. Valence (i.e., feeling better) was neither associated with physical activity nor predictive of subsequent physical activity. At the between-person level, the multilevel analysis revealed that individuals with higher levels of physical activity than the group average had significantly higher levels of energetic arousal. In the model analyzing the influence of valence, energetic arousal, and calmness on physical activity, we found no meaningful between-person results. The results of this EMA study support the hypothesis of a bi-directional association between physical activity in daily life and energetic arousal and calmness in individuals with overweight and obesity, as it has been repeatedly found in studies of individuals within the normal weight range. In contrast to prior literature, we did not find an association between valence and physical activity.

As physical activity is a key health behavior in the treatment of overweight and obesity to support and especially maintain weight loss, exercise therapy is a relevant pillar in the treatment of overweight and obesity as suggested by national and international treatment guidelines (DAG, 2024; Durrer Schutz et al., 2019; Semlitsch et al., 2019). In addition to structured exercise, low-level physical activity in daily life, and thus an increase in non-exercise activity thermogenesis (NEAT), contributes to greater energy expenditure (Chung et al., 2018). Identifying predictors of physical activity in daily life is therefore important to increase the engagement and adherence to treatment. Our finding that everyday physical activity is

associated with affective determinants, i.e., energetic arousal and agitation, is relevant in that it deepens the understanding of what facilitates and prevents individuals with overweight and obesity from being more active in daily life. It also strengthens the assumption that affect and physical activity behavior are interrelated and that affective responses to physical activity should be targeted in interventions for individuals with overweight and obesity (Ekkekakis & Zenko, 2016).

The null finding between valence and physical activity in our study is particularly interesting as it challenges the assumption that increased movement leads to feeling better. Previous EMA studies have found a reciprocal relationship between physical activity and valence in individuals with higher weight (Carels et al., 2007; Emerson et al., 2018; Liao et al., 2015). Two aspects that may explain these conflicting findings were discussed in detail in Study 1 (see Chapter 2). First, methodological differences between studies (i.e., study design, self-reported vs. device-measured physical activity), and second, the assumption that physical activity has a different temporal effect on dimensions of core affect in individuals with overweight compared to those with a BMI < 25 kg/m^2. As higher body weight is associated with a range of physical and psychological discomforts (Ekkekakis et al., 2016), it may be that valence is not immediately increased after engaging in physical activity. In turn, this repetitive experience may be the cause of less motivation to increase physical activity in the future as it is less intrinsically rewarding (Conroy & Berry, 2017; Stevens et al., 2020). In summary, our findings highlight the important time-varying association between dimensions of core affect and measures of physical activity. However, the lack of a control group limits our ability to draw causal conclusions. In addition, there are a number of moderators and mediators that may influence this relationship. For example, exercise intensity, perceived autonomy, and contextual or situational influences such as social environment have been suggested to moderate the relationship between physical activity and core affect (Bourke et al., 2021; Reichert et al., 2020; Timm et al., 2024). It would be important to assess these variables in future studies to distinguish the associations in more detail.

Further EMA studies in this area are needed to investigate the aforementioned moderators and mediators and to clarify the causal relationships between physical activity and affective determinants of overweight and obesity. However, our findings support cautious conclusions that can be considered in the development and design of mHealth interventions in obesity treatment. The bi-directional relationship between an increase in physical activity through an increase in energetic arousal and agitation can be strengthened by providing affect-enhancing

strategies in an intervention. For example, by addressing core affect as a proxy for physical activity engagement, digital interventions could offer guided mental imagery scripts, highly arousing music, or video clips to induce affective states such as arousal (Duncan et al., 2012; Giacobbi et al., 2018; Lundqvist et al., 2009). In addition, digital physical activity interventions should allow for regular assessment of core affect in order to recommend physical activity interventions at moments when a person is particularly agitated and/or energetically aroused. This tailoring can be achieved through the implementation of just-in-time adaptive interventions (JITAI). These highly personalized types of interventions aim to maximize the relevance and usefulness of the interventions delivered by providing behavior change support at the most promising time for a desired behavior (e.g., physical activity; Hardeman et al., 2019; Nahum-Shani et al., 2015). Wunsch and colleagues' (2022) definition of JITAIs includes being responsive to real-time needs, adaptive to input data, are system-triggered, goal-directed, and tailored to user preferences. Applied to our findings, mHealth interventions to increase physical activity in individuals with overweight and obesity should automatically trigger JITAIs when a user reports high levels of energetic arousal and low levels of calmness, track physical activity through sensors, assess affect when physical activity levels are high, provide feedback to the users about the association between physical activity levels and affect, and enable customization (e.g., select time frames when triggers are muted).

As described above, the fact that our analysis did not show a significant relationship between physical activity and valence suggests that the affective response of an individual with overweight or obesity to physical activity may not be to feel immediately better and may even evoke negative emotions (Ekkekakis et al., 2016). However, this hedonic reward is often communicated to participants in physical activity programs: The more you exercise, the better you will feel. In order to create realistic outcome expectations among participants, it is important to communicate that this expected "feel good" effect may not initially manifest in individuals with overweight and obesity. Klusmann and colleagues (2015) showed that the fulfilment of emotional outcome expectancies is a significant predictor of successful behavior change. Therefore, each individual's affective attitude toward physical activity should be assessed and addressed accordingly in interventions with either cognitively or affectively framed health messages (Morris et al., 2016; Yubing Wang et al., 2023). The latter should then focus on self-monitoring other facets of core affect, such as energetic arousal or calmness, to strengthen participants' self-efficacy. It is likely that communicating realistic goals and

expectations will lead to less frustration among participants and thus higher adherence and acceptance of digital interventions (Klusmann et al., 2015).

6.2 Research Question 2: Use and Acceptance of a Gender-Sensitive Psychological mHealth Intervention

How did the participants use and accept the psychological mHealth intervention I-GENDO and how did they use the gender-sensitive tailoring features of the intervention?

The second original study (see Chapter 3) presented the development and process evaluation of the 12-week self-guided gender-sensitive psychological mHealth intervention I-GENDO. The development process of the app is described in detail in the article (Pape et al., 2022). During the development of the app, we placed particular emphasis on two aspects: the selection of evidence-based psychological treatment components and the implementation of a gender-sensitive approach.

As presented in Chapter 1.2.2, the treatment of overweight and obesity is based on a multimodal approach that combines nutrition, exercise, and behavioral therapy (Durrer Schutz et al., 2019). To increase the effectiveness of such lifestyle interventions the incorporation of more comprehensive psychotherapeutic treatment components that enhance the understanding and modification of the psychological drivers of health behaviors is promising (e.g., Becker et al., 2015). Therefore, for the I-GENDO mHealth intervention, we selected evidence-based psychotherapeutic treatment components that have been used in previous CBT-based weight loss interventions (e.g., Becker et al., 2015; Z. Cooper & Fairburn, 2001; Munsch & Hilbert, 2015; Preuss et al., 2018). The final mHealth intervention consisted of seven psychological modules (*goal setting*, *stress management*, *emotion regulation*, *consequences of having overweight*, *self-efficacy*, *self-regulation skills*, *and relapse prevention strategies*) that target individual emotional and cognitive factors associated with the development and maintenance of overweight and obesity. The modules included a variety of BCTs and CBT-based treatment strategies, such as psychoeducation, stress management, problem solving, mindfulness, behavioral experiments, self-monitoring and goal setting. The general use of BCTs has been shown to increase the effectiveness of mHealth interventions (Dugas et al., 2020; Lyzwinski, 2014). The most commonly used BCTs in weight-loss programs are feedback, self-monitoring, goal setting, direct provision of information or behavioral instruction, and social support (Berry et al., 2023; Qin et al., 2022). However, more research is needed to disentangle the effects of specific BCT combinations on weight loss, as there is a large overlap of techniques between

effective and ineffective mHealth interventions (Dugas et al., 2020; Qin et al., 2022). At the time the I-GENDO app was developed, there were only a few digital psychotherapeutic treatment approaches. In recent years however, more mHealth interventions have been developed and evaluated (Ebrahimi et al., 2023; Forkmann et al., 2022; Gemesi et al., 2024; Hilbert et al., 2023; Roth et al., 2023). The majority of them focus on CBT (Ebrahimi et al., 2023), but there have also been digital programs implementing third-wave cognitive behavioral interventions such as Acceptance and Commitment Therapy (ACT; e.g., Richards et al., 2022) or Mindfulness-Based Cognitive Behavioral Therapy (MBCT; Lyzwinski et al., 2018b).

To date, however, there are few mHealth interventions that technically implement gender-based individualization. We have implemented a gender-sensitive approach in the I-GENDO app to enable individualization of the intervention with respect to sex/gender aspects. This novel gender-sensitive approach was designed so that each of the seven modules were presented in either a female-targeted or male-targeted variant, which differed in terms of transfer of content (e.g., detailed presentation of emotional competences in the male-targeted variant), delivery style (e.g., differences in language and multimedia elements), and prioritization of topics. The content design was informed by an extensive literature review on sex/gender differences in overweight and obesity and focus groups conducted early in the development phase.

The I-GENDO app allowed for gender-sensitive customization through human tailoring (K. Ryan et al., 2019). While using the app, female and male users of the I-GENDO intervention had to choose the variant to proceed with at the beginning of each module. For this selection process, they received a short description of each variant. However, the users were not informed about the underlying gender-sensitive approach and hence were able to choose the variant that appealed to them more, regardless of their biological sex. The decision to implement such a gender-sensitive approach was based on the fact that there is a large body of literature on how sex/gender influences perception, treatment expectations, and lived consequences of obesity (A. J. Cooper et al., 2021) which has not sufficiently been addressed in existing digital interventions (J. Wang et al., 2020). In a scoping review, Urban (2021) highlights the need for gender-sensitive digital health approaches to reduce unintended negative consequences, narrow the health gap, and avoid deepening structural inequalities. The author notes that there is no checklist or a simple set of recommendations for developing such interventions, but rather a long-term learning process and reflection on technology development and implementation (M. Urban, 2021).

Here, the experience gained from diabetes self-management can inform gender-sensitive development of mHealth interventions. For example, a qualitative study found that women and men differ with respect to their information sources and knowledge gains and that they desired different topics in mHealth intervention content that considered their specific challenges to overcome diabetes (Burner et al., 2013). In the *DIABGender* project, a prototype of a gender-sensitive diabetes self-management app was proposed (Zauchner-Studnicka et al., 2016). The app offered event-based, gender-sensitive behavioral tips to users. For example, low self-efficacy tends to be more prevalent in women, therefore in a sex/gender-specific approach, only women would receive self-efficacy behavioral tips while men would not. Users of the *DIABGender app*, on the other hand, would indicate their level of self-efficacy and receive event-based tips regardless of their sex/gender. The offered behavioral tips were then individualized according to personal interests and needs. This approach ensured that the tips were not sex/gender-specific and that everyone with diabetes, regardless of type or sex/gender, had access to them (Zauchner-Studnicka et al., 2016).

To answer the proposed Research Question 2 of how the I-GENDO app in general and the gender-sensitive tailoring features were used, and whether the app was accepted, I will now discuss and classify the data presented in Study 2. 77 women and 39 men with overweight or obesity (BMI: 33.58 kg/m^2) were randomized to the intervention group and had access to the I-GENDO intervention. Analysis of the app data showed that, 109 of 116 users (94%) used the app at least once during the 12-week intervention period. Detailed analysis of app use showed that 83% of individuals met the adherence criteria (i.e., at least 12 actions within the app and at least 120 minutes of app use) and that a meaningful decrease in frequency and duration of use was observed over the course of the 12-week intervention. This observed pattern of app use has been reported in other digital intervention studies in the context of diabetes self-management (Butryn et al., 2020; Signal et al., 2020) and describes a known challenge in self-directed mHealth interventions (Han & Rhee, 2021; Lee et al., 2018; Meyerowitz-Katz et al., 2020). Gemesi and colleagues (2024) suggest that the observed decline represents a saturation effect, as the benefits of behavior change diminish over time. It has been repeatedly demonstrated that higher engagement with self-monitoring features of mHealth apps (e.g., monitoring lunch, body weight, exercise) leads to both less decline in app use and more weight loss over time, suggesting the value of self-monitoring features in mHealth interventions (Han & Rhee, 2021; Lee et al., 2018). In addition, there is ample evidence that when human social or emotional support is implemented within an intervention, compliance and adherence to an mHealth

intervention increases (Berry et al., 2023; Firth et al., 2017; Lindhiem et al., 2015; Schippers et al., 2017).

We identified significant sex/gender differences in app usage. On average, female participants used the app for more minutes (M = 624.85, SD = 427.94) than male participants (M = 346.69, SD = 285.68). Consequently, more actions within the app were recorded for women (M = 96.51, SD = 88.03) than for men (M = 55.98, SD = 45.62). Previous findings on sex/gender differences in app usage behavior in the health context are consistent with our results (e.g., Stühmann et al., 2020). It has been shown that women tend to use the internet and apps more often than men to search for health-related information (Bidmon & Terlutter, 2015; Ek, 2015). In terms of specific types of mHealth apps, women are more likely to use health, nutrition, and self-care apps, while men use fitness apps (Bol et al., 2018; Carroll et al., 2017; Escoffery, 2018; Stühmann et al., 2020).

The overall satisfaction with the I-GENDO app was rated at 86/100 (n = 41). On average, the usability of the app was rated as 5 out of 7 points by both female and male participants. The overall adherence (83%), satisfaction (86%), and usability (71%) ratings of the I-GENDO app indicate that the intervention was generally accepted by the users. A recent review shows that mHealth interventions for weight management generally have high scores for acceptability, perceived usefulness, and satisfaction, which supports their feasibility (Dounavi & Tsoumani, 2019). However, comparing these acceptability and usability scores across mHealth interventions is difficult because the composition of interventions is so heterogeneous, and different measures and definitions of usability and adherence are used (Zhou et al., 2019). As the number of digital weight management interventions developed in recent years has grown, it has become increasingly apparent that they key to increasing usage and adoption is to involve end-users at every stage of the research and decision-making process to design interventions that are relevant to the target audience (Deniz-Garcia et al., 2023). This research approach is called participative research or patient and public involvement (PPI). To ensure PPI, a project should be designed from the outset so that decision-making processes are shared with co-researchers (Baines et al., 2022; M. T. Wright & Kongats, 2018). In the development of the I-GENDO app, a preliminary stage of participatory research was carried out: user-centered design (UCD; McCurdie et al., 2012). The aim of UCD is to identify the needs of the target group and to define characteristics and features of the intervention that are accepted by the end users (McCurdie et al., 2012). In the long term, this results in an increased likelihood that the intervention will actually be used and that the relevance is higher (Deniz-Garcia et al., 2023).

A suitable way to identify user needs is through focus groups (Langford & McDonagh, 2005). For the I-GENDO intervention we conducted focus groups with female (n = 18) and male (n = 12) participants which have successfully lost weight (i.e., weight loss of at least 10% for at least six months) or regained weight after weight loss. Women and men were asked about facilitators and barriers which have influenced their own weight management. Using qualitative content analysis (Mayring & Fenzl, 2019), we identified gender-specific strategies and cognitive and emotional processes which were then implemented in the I-GENDO mHealth intervention. Assessing the needs and expectations of the I-GENDO intervention at the beginning of the development process was valuable in promoting participant-driven rather than theory-driven development of weight loss programs, which is recommended but lacking in the development of gender-sensitive weight management interventions (Chew et al., 2022; Nguyen et al., 2024). However, according to UCD, it would have been valuable to conduct usability testing in the later stages of development and have users test a prototype of the app and key features of the intervention to ensure that the content developed and its implementation was understandable and relevant to users (McCurdie et al., 2012).

Regarding the selection of gender-specific variants in the I-GENDO intervention, the female-targeted variants were selected in 58% (163/280) of the choices. Interestingly, there was no meaningful difference in selection behavior between female (116 of 196 female-targeted variants; 59%) and male participants (47 of 84 female-targeted variants; 56%). Hence, our results show that participants did not consistently select module variants according to their sex/gender. This result can be interpreted in a variety of ways. First, the results may indicate that the implementation of gender-sensitive approaches, as proposed by Urban (2021) and Hyde and colleagues (2019), is useful to counteract sex/gender binaries. Second, there are methodological issues to consider in the technical implementation of the gender-sensitive modules of the app. In all seven modules, the order was such that the female-targeted variant was presented before the male-targeted variant. It is therefore possible that a sequence effect occurred that was unrelated to the content. This needs to be tested with a randomized order. It should be discussed whether the short text shown to the users was sufficient to enable them to make an informed decision about the content of each variant, or whether more information should have been provided. Third, we systematically assessed sex/gender differences in overweight and obesity in literature reviews and conducted focus groups with the aim to consider sex/gender differences in the prevalence and treatment of overweight and to move away from the dichotomous sex/gender categories. However, we did not communicate this

tailoring to users and did not provide detailed information about the critical characteristics used for customization, as suggested by Beck and colleagues (2010). For further mHealth studies that intend to build on these initial results of an innovative gender-sensitive approach, it would be important to validate and test the gender sensitivity in a preliminary study. For follow-up projects, it would also be interesting to consider the possibilities offered by artificial intelligence (AI), which increases the potential to personalize content to the needs of the end users in obesity treatment (Deniz-Garcia et al., 2023; D. M. Thomas et al., 2024).

In summary, developing a mHealth intervention with a gender-sensitive approach for individuals with overweight and obesity presents an innovative and promising approach. By following an iterative development process in an interdisciplinary team, we have implemented an important step in the development of digital interventions. Although our study provides only preliminary evidence on whether our gender-sensitive approach is feasible in mHealth intervention and whether this feature improves the acceptability of an intervention, the gender-sensitive approach addresses the increasing relevance of recognizing sex/gender in obesity and health research and reduces social desirability bias (Miani et al., 2021; M. Urban, 2021). It also contributes to the goal postulated by guidelines and by individuals with overweight and obesity themselves: It is the task of clinicians and practitioners to enable individuals who want to lose weight in the long term to find an individually holistic approach to behavior change treatment (Chew et al., 2023). By incorporating sex/gender aspects, it is expected that mHealth interventions will provide their users with individualized tips and suggestions to enable better and more individualized self-management of obesity.

6.3 Research Question 3: Effect of the I-GENDO Intervention on Eating Behavior, Physical Activity and BMI

How did using the psychological mHealth intervention I-GENDO affect changes in eating behavior (i.e., emotional eating, restrained eating, and external eating), physical activity and BMI over 15 months?

The results of the RCT presented in Study 3 (see Chapter 4) showed that addressing cognitive and emotional factors through the novel I-GENDO mHealth intervention led to differential effects on eating behavior and BMI in women and men with overweight and obesity. Female and male participants who used the mHealth intervention I-GENDO for 12 weeks reported a significant increase in restrained eating after the intervention and at 9 months follow-up. A significant decrease of external eating was observed in the female users for all three

assessment points. At 9 months follow-up, emotional eating was lower in the intervention group than in the control group among women. No sustainable change in emotional eating or external eating was observed for the male participants in the intervention group. However, the BMI of the men in the decreased significantly compared to the men in the control group at all three assessments. No changes in BMI over time were observed in the female participants. Taken together, the I-GENDO intervention effectively improved restrained eating, emotional eating and external eating in women and increased restrained eating and decreased BMI in men in the long-term, and decreased external eating in men in the short term.

The finding that the usage of the mHealth intervention increases ratings of restrained eating over almost 15 months is promising as increased levels of restrained eating predict weight loss and successful weight loss maintenance (James et al., 2018; Teixeira et al., 2010; van Strien et al., 2009). It strengthens the assumption that cognitive aspects in obesity treatment (e.g., self-regulation skills, inhibitory control) may be underlying aspects which influence eating behavior such as overeating (Dohle et al., 2018). The intervention effect on restrained eating was present in both women and men. However, the increase in restrained eating in our study was not linked to weight loss in women, contrary to other studies (James et al., 2018).

Women in the intervention group reported significantly lower levels of emotional eating at 9 months in comparison to the women in the control group. No meaningful changes were observed for male participants. The difference in intervention effect might reflect the proposed sex/gender differences in emotion regulation and emotional eating in individuals with overweight and obesity (Ayyıldız et al., 2023; Christensen & Brooks, 2006; Cotter & Kelly, 2018; J. K. Larsen et al., 2006). The answer to the question of why the effects on emotional eating did not last until the follow-up assessment remains speculative. As discussed in Study 3, it is reasonable to assume that the implementation of emotional regulation strategies within the I-GENDO app was not as feasible as the implementation of more cognitive strategies (Rathbone et al., 2017). Although there are digital interventions that have successfully integrated emotional strategies into apps (e.g., Cook et al., 2019; Lyzwinski et al., 2019) and CBT has been shown to reduce emotional eating (J. Smith et al., 2023), we hypothesize that lasting change in emotional processing will require deeper, more complex, and more personalized treatment approaches in combination with human social and emotional support (Schippers et al., 2017). In addition, the implementation of ACT-based strategies may be promising to reduce emotional eating, particularly when identifying individuals with high emotional eating scores (Forman & Butryn, 2015; Iturbe et al., 2022; Järvelä-Reijonen et al., 2018).

The intervention had a short-term effect on external eating behavior for both male and female participants. External eating behavior is driven by high sensitivity to food cues and low food-related inhibition (van Strien et al., 1986). The desired changes in this behavior may be due to the fact that the majority of male and female participants (90%) engaged with the module *self-regulation skills*. However, our findings show that the intervention effect on external eating was only valid in the short-term for male participants. As discussed in Study 3, one possible explanation for this sex/gender difference in treatment retention is the assumption that the women benefited more and were more open to the mindfulness interventions offered that enhance the ability to perceive internal cues and thus affect external eating (Vonderlin et al., 2020). However, this assumption is challenged by the results of a recent meta-analysis that found no sex/gender effect for mindfulness-based programs (Galante et al., 2023).

The I-GENDO intervention had an overall positive effect on eating behavior change, but the variability of results highlights the need for a better understanding of the underlying psychological processes and the identification of effective psychotherapeutic treatment components. These findings reemphasize the need to emphasize emotional treatment strategies in digital weight loss interventions such as those implemented in third-wave CBT approaches such as Dialectical Behavioral Therapy (DBT), ACT, or MBCT (Forman & Butryn, 2015; Forman et al., 2015). A key feature of these third-wave interventions is that participants are encouraged to accept, rather than avoid, aversive internal experiences (e.g., negative emotions; Forman et al., 2015). In addition, elements of mindfulness are implemented to improve the individual's perception of internal and external cues to eat (Forman et al., 2015). The goal of DBT-oriented interventions is for individuals to first learn to identify cognitions and emotions that precede and follow an eating episode and to regulate them with adaptive emotion regulation strategies (i.e., skills) before beginning a behavioral weight loss intervention (Braden et al., 2020; Braden & O'Brien, 2021). Face-to-face MBCT-based group programs are effective in reducing binge eating, external eating and emotional eating (Frayn & Knäuper, 2018). Carriére and colleagues (2018) found that mindfulness-based interventions led to decreased rates of maladaptive eating behaviors as well as weight loss. A recent systematic review and network meta-analysis found that such third-wave CBT interventions for weight loss resulted in greater weight loss than no intervention and standard behavioral weight loss programs at post-intervention and at 12- and 24-month follow-up assessments for both women and men (Lawlor et al., 2020). Based on these findings, it may be promising to offer third-wave intervention strategies in a more structured and frequent manner in an mHealth intervention.

Although the reduction of one BMI point from baseline to 15 months in male participants is not clinically significant, as it represents less than 5% of body weight lost, the difference from the control group was statistically significant at all three assessments. Notably, we did not find this interaction effect in the female intervention group. In line with our findings, the evaluation of the recently developed mHealth interventions *zanadio* and *Oviva Direct für Adipositas* showed an overall greater weight loss in male participants than in female participants (Forkmann et al., 2022; Gemesi et al., 2024; Roth et al., 2023). Both of these interventions were developed and evaluated as part of the innovative German concept of Digital Health Applications (DiHA; Forkmann et al., 2022; Gemesi et al., 2024; Roth et al., 2023). DiHAs are low-risk medical devices that are reimbursed by all public health insurers and provide low-threshold access to evidence-based content for individuals with overweight or obesity. Germany was the first country to introduce these DiHAs, which can be prescribed by physicians and psychotherapists (Ludewig et al., 2021). Thus, both interventions represent a promising implementation of evidence-based treatment strategies delivered via mobile phone, which could reduce the gap in care for multimodal treatment of overweight and obesity described in Chapter 1.4. *zanadio* is a 12-month program that focuses on knowledge transfer about diet, exercise, and behavior on weight loss behavior through e-learning modules, self-monitoring features to assess behavior, goal setting and motivation, and support from health professionals via chat. Real-world data (n = 11.323) showed that *zanadio* is predominantly used by women (79%) and individuals with a mean average BMI of 36.6 kg/m^2 (Forkmann et al., 2022). In an RCT (n = 150, 90.67% female), *zanadio* was tested against a wait-list control group. Use of the 12-month program resulted in a clinically meaningful weight loss of 7.75% and improvements in well-being and quality of life in the intervention group (Roth et al., 2023). *Oviva Direkt für Adipositas* is a 12-week long multimodal intervention that focuses on three main elements: self-management, self-monitoring of diet, physical activity and body weight, and knowledge transfer (e.g., etiology of obesity, coping with relapse). The app was tested in an RCT (n = 168, 64.3% female). After 12 weeks, the intervention group lost 2.6% of their baseline body weight, with men losing significantly more weight than women (Gemesi et al., 2024). This provides further evidence that the use of psychological interventions leads to successful weight loss in men. Previous literature suggests that, when men participate in weight loss programs, they lose more weight than female participants (Chopra et al., 2021; Stroebele-Benschop et al., 2013; Williams et al., 2015). The low number of male participants in both the real-world data (Forkmann et al., 2022) and the RCTs (Gemesi et al., 2024; Roth et al., 2023) is another

indication that men are not being reached by current (digital) interventions (Pagoto et al., 2012). Based on these findings, the question of how to motivate male participants to participate in (digital) weight-loss interventions is reinforced.

With regard to the I-GENDO intervention, the weight loss observed in men, but not in women, is notable because female participants in the intervention group showed a more sustained improvement in eating behavior, and, as discussed in Chapter 6.2, female participants used the I-GENDO intervention more often and more intensively than male participants. These results may indicate that deeper and more thorough engagement with the app's content led to lasting changes in eating behaviors, but not changes in weight. This finding contradicts our assumption that addressing the underlying psychological mechanisms would change health behaviors (i.e., physical activity, eating behaviors), which in turn would affect weight. Given these conflicting results, further studies are needed to determine the degree of app use necessary to successfully change health behavior and weight (Mattila et al., 2016).

Taken together, the results of our RCT showed that the use of the gender-sensitive psychological I-GENDO intervention had an effect on restrained, emotional, and external eating behavior in women and partially in men, and on BMI up to 15 months in male participants. No meaningful group differences were observed for physical activity. Considering our gender-sensitive approach, these heterogeneous intervention effects raise further research questions. With our current study design, the conclusions we derive about the effects of gender sensitivity and individualization on our outcomes remain speculative. However, our study provides a counter-proposal to the majority of existing interventions that do not take sex/gender differences in account (Opozda et al., 2024; M. Urban, 2021). Instead of gender-specific interventions, we tested the effectiveness of a gender-sensitive app that allowed men and women to customize intervention content based on individual needs and life realities. Gender sensitivity translates well to mHealth technologies because they allow users to customize content based on their individual needs and perceptions, rather than assigning independent gender-specific interventions to women and men. In terms of changing cognitive and emotional aspects related to overweight and obesity, our findings suggest that our novel self-guided, gender-sensitive approach holds promise for changing cognitive aspects (i.e., self-control). Questions remain about the impact of gender-sensitive individualization on intervention effectiveness and how mechanisms of emotion regulation can be modified within an mHealth intervention.

6.4 Research Question 4: Implications for Assessment and Intervention Studies in the Context of Overweight and Obesity

What conclusions can be drawn from the current state of knowledge regarding the acceptance, use and effectiveness of future digital solutions for the assessment and treatment of overweight and obesity?

The growing number of digital interventions in the context of mental health presents several challenges. Despite the potential of digital approaches to provide low-threshold access, geographic independence, and cost-effectiveness, there are significant barriers to their effective implementation. A key challenge is the lack of standardized guidelines and methodological quality, which creates uncertainty about the validity and appropriateness of different digital tools (K. A. Smith et al., 2023; Torous, 2022; Torous et al., 2021; Torous et al., 2023). In addition, many clinicians and practitioners feel unprepared to integrate digital solutions into their practice due to inadequate training and skepticism about the effectiveness of these technologies (Mendes-Santos et al., 2022). It is also difficult to distinguish evidence-based digital interventions from a vast array of invalidated options, leading to potential risks in clinical settings. Concerns about data security, privacy, and the impact of digital tools on the therapeutic relationship further complicate the adoption and use of these technologies in mental healthcare (K. A. Smith et al., 2023).

The expert consensus presented in Study 4 (Chapter 5) was conducted with the goal of promoting methodological quality, evidence, and sustainable implementation of technological innovations in mental healthcare. An adapted, structured, nine-step Delphi process was used to reach consensus among 25 authors with expertise in digital mental health. The manuscript provides a practical guidance for the design and evaluation of digital mental health interventions and assessments. It emphasizes the need for high-quality evidence through rigorous study designs, such as RCTs, to assess the effectiveness and safety of digital solutions. For intervention development, we discussed the importance of involving end users (i.e., PPI), adopting a user-centered approach, considering therapist involvement, and personalizing digital tools to improve adherence and outcomes. For assessment studies, the focus is on using technologies such as mobile sensing and EMA to obtain real-time data on users' mental states and behaviors, and allowing for more precise and dynamic monitoring. The guidelines emphasize the importance of ethical considerations, data security, and methodological rigor to improve the reliability and effectiveness of e-mental health tools.

The development of the guidelines presented in Study 4 (see Chapter 5) was based on an extensive literature review and the experience of the 25 authors in developing and evaluating a range of digital health approaches. In particular, lessons learned from both the assessment study (Study 1) and the intervention studies (Study 2 and Study 3) in the I-GENDO project were incorporated and applied to the development of the guidelines. In the following, I will discuss the selection of the target group, the implementation of the EMA, the selection of the control group in the RCT, and the format of the mHealth intervention itself to illustrate how the experiences in the I-GENDO project have influenced the development of the recommendations proposed in Study 4.

Before conducting a mHealth assessment or intervention study, researchers should reflect on various questions that lead their decision making throughout the planning process. In Study 4, such a step-by-step approach was proposed, which covers essential aspects when planning a study. Following this proposed conceptualization process, the first two steps when planning a mHealth study are to define the objectives, theory and hypotheses and to define the target group. Derived from that, researchers are able to decide which digital functions and qualities are necessary for their research: assessment or intervention or both. The target group of the studies presented in this dissertation are individuals with overweight and obesity, and the research questions focused on the association between emotional and cognitive processes and weight-related behavior (i.e., physical activity). Digital treatment approaches are promising for this population (Hinchliffe et al., 2022; Irvin et al., 2023) as the prevalence of overweight and obesity is increasing without an adequate increase in existing psychological treatment options (Blüher, 2021; Nolting et al., 2016). In addition, the development and maintenance of weight is multifactorial, and the links between behavior and emotional and cognitive aspects remain to be fully understood (Hall et al., 2022; Stroebe, 2022). mHealth represents a holistic approach to assessing and changing these psychological aspects and behaviors in daily life, which could complement existing structures and clinical care in the treatment of overweight and obesity. Previous research has shown that there are consistent sex/gender differences in the prevalence, experiences, exposures, health outcomes, treatment, and maintenance of overweight and obesity, as well as in the emotional and cognitive processes associated with weight and weight-related behaviors (A. J. Cooper et al., 2021), which have not yet been considered in digital approaches (M. Urban, 2021).

One experience from the I-GENDO project was that the selection of an EMA study design (see Chapter 2) was feasible to investigate the momentary bi-directional association between a

particular behavior (i.e., physical activity) and core affect in everyday life. This is a typical use case for an EMA study as the combined assessment of continuous real-time data on behavior and repeated measurement of subjective experiences is more sensitive to capturing change and thereby provides a detailed picture of mental state and functioning (Myin-Germeys & Kuppens, 2021; Trull & Ebner-Priemer, 2013). We chose the tri-axial ActiGraph® wGT3X-BT accelerometer to measure physical activity coupled with a validated self-reporting questionnaire (i.e., German short scale of the Multidimensional Mood Questionnaire; Wilhelm & Schoebi, 2007) to assess core affect (i.e., energetic arousal, calmness, valence). Accelerometers allow for the non-invasive collection of high-frequency longitudinal data on human behavior (i.e., physical activity). As described in Study 4, an ongoing challenge is the standardization of the assessed data due to change in hardware or user behavior. One benefit of using off-the-shelf devices is that users are already used to wearing these in their everyday life. However, the Actigraph accelerometers are better validated for research contexts and comply with data protection regulations (Aadland & Ylvisåker, 2015; Cleland et al., 2013), but must be worn as external devices, which can affect compliance (Wrzus & Neubauer, 2023). For the assessment of core affect within the survey, we adjusted the instruction of the questionnaire as we wanted to assess the 15-minute interval prior to the assessment (i.e., referring to a specific time frame). Next to the length of the questionnaire, the number of assessments per day and the assessment epoch needs to be decided on as it influences compliance rates (Myin-Germeys & Kuppens, 2021). In our study, we assessed core affect eight times per day. This decision was based on previous EMA studies which investigated the bi-directional association between core affect and physical activity (Liao et al., 2017). It is crucial that the sampling strategy fits the temporal dynamics of the underlying process (Myin-Germeys & Kuppens, 2021). However, it cannot be conclusively determined whether this was the case in our study, as the underlying mechanisms and processes between affect/mood and physical activity are not yet fully understood (Brose et al., 2020; Kim et al., 2020). Hence, we decided on this pragmatic approach. In our EMA study, we combined two different sampling schemes: time-based (i.e., surveys are sent at predefined times) and event-based (i.e., users answer the survey when a specific event, such as increased physical activity is present). Combining sampling schemes is valid when the behavior being studied is assumed to be both present during a given time frame and initiated by an individual (Kockler et al., 2018). With respect to our research questions in Study 1 (i.e., bi-directional association between physical activity and core affect), this sampling scheme is not entirely appropriate. The reliability of the data could have been increased by

choosing a time-based sampling scheme rather than a combined sampling scheme. In addition, the assessment period was not time-limited, which meant that participants could answer the questions whenever they chose to. Other EMA studies allow participants to actively delay or decline alarms, but the surveys time out after a certain amount of time. We controlled for this in our statistical analyses and deleted assessments that were less than 30 minutes apart. However, participants completed a greater number of questionnaires than were ultimately included in the analysis. To reduce participant burden, future assessment studies should select these important decisions about sampling design, questionnaire length, and number of assessments more carefully when designing an EMA study in the context of overweight and obesity (Wrzus & Neubauer, 2023). The discussion of the findings of the EMA study showed (see Chapter 6.1) that the detailed knowledge about momentary associations between affective determinants and health behavior can inform the design and development of mHealth interventions in overweight and obesity treatment.

Study 2 and Study 3 presented the development and evaluation of the gender-sensitive mHealth intervention I-GENDO. Overall, by addressing psychological factors of overweight and obesity through the I-GENDO intervention, improvements in eating behavior and small reductions in initial weight were achieved. The described results provide valuable starting points for the further development of gender-sensitive psychological mHealth interventions in the area of overweight and obesity. However, the effects were mixed regarding their sustainability, and they also differed by sex/gender. In addition, the design of the evaluation study (see Chapter 4) limits conclusions about the extent to which the effects found are related to individualization (i.e., gender sensitivity) and makes explaining the sex/gender differences difficult. A comprehensive evaluation of an mHealth solution – as we did with the I-GENDO intervention - is critical, as there is a wide range of commercial and non-evaluated apps that could potentially harm users (Kumar et al., 2013). The most common approach for testing the effectiveness of an mHealth intervention is a RCT (Kupila et al., 2023; Pham et al., 2016), where individuals are randomly assigned to the intervention group and at least one control condition.

For the evaluation of the I-GENDO intervention we chose a RCT with two study arms: intervention and control group. Participants in both groups were allowed to continue with diet and/or exercise therapy (i.e., treatment as usual). The definition of the control group is a critical decision point in RCTs in mHealth research (Goldberg et al., 2023). According to the typology proposed by Goldberg and colleagues (2023), the design of the control condition can take a

variety of forms depending on whether it is intended to be therapeutic (e.g., offer another mHealth intervention with minimal or comparable efficacy, active treatment as usual, delivery of evidence-based treatment) or not (e.g., no treatment, placebo-minimal). In the I-GENDO study, we evaluated the effectiveness of the mHealth intervention with all its intervention components and compared it to the control group that received treatment as usual. According to the typology, this choice of control condition implies a low comparison strength. The strongest comparison strength would be achieved if the control group followed a dismantling or additive design, which means that specific intervention components are subtracted or added and tested against the intervention (Goldberg et al., 2023). Because we selected a control group with very low comparison strength, we cannot conclusively determine the specific content of the I-GENDO intervention that is effective. To test the effectiveness of the specific features of the app (i.e., individualization and/or gender-sensitivity), different control groups would have been necessary.

By comparing the usage of the I-GENDO intervention to treatment as usual we cannot derive if the individualization features or the gender-sensitivity were decisive aspects of the intervention. The intervention itself remains a "black box", and intervention content is not untangled (Sieverink et al., 2017). In mHealth research, however, the question of which specific single characteristics and content of an intervention are effective becomes more and more relevant (Dugas et al., 2020; Mair et al., 2023). An example study design to specifically test these individualization and gender-sensitivity features would include six study arms: 1) male participants + female-targeted modules, 2) female participants + female-targeted variants, 3) male participants + male-targeted modules, 4) female participants + male-targeted modules, 5) male participants + human tailored module assignment and 6) female participants + human tailored module assignment. The advantage of such a control group design would be to draw conclusions about the implementation of the individualization and the gender-sensitive features. Because excessive resources would be required for such a study design, approaches from the field of engineering, such as the Multiphase Optimization Strategy (MOST) are becoming more widespread (Collins, 2018). MOST is a framework for creating more efficient, effective, cost-effective and scalable behavioral interventions (Collins, 2018). It allows researchers to choose an optimization criterion and makes it easier to choose which components to include in an intervention.

In addition to the study design, there are also aspects of the I-GENDO intervention itself that informed the development of the guidelines. We decided to develop the I-GENDO

intervention as a self-guided intervention because it should work as a standalone intervention. This allowed users to work independently with the topics of the app and add them to their own individual weight management (e.g., nutrition or exercise program). Self-guided mHealth interventions have been shown to be more effective in comparison to wait-list control groups or treatment as usual (Lindhiem et al., 2015). However, when directly compared to guided interventions, meta-analysis in the field of mHealth have repeatedly demonstrated that self-guided interventions are used less frequently and effect sizes are smaller (Firth et al., 2017; Schippers et al., 2017; J. H. Wright et al., 2019). The guidance in mHealth interventions is typically offered by psychologist or coaches that provide written or personal feedback to the user's activity in the app. In general, this approach requires more human resources, and it must therefore be considered whether these can also be guaranteed beyond the project phase (Schippers et al., 2017). As there are generally fewer resources available for the treatment and psychological healthcare of overweight and obesity (Frood et al., 2013; Nolting et al., 2016), this should be taken into account when planning an intervention project. In recent months, many new innovative AI approaches have been presented that could potentially compensate for the "guidance" factor in obesity care (Hinchliffe et al., 2022; D. M. Thomas et al., 2024).

The experiences and lessons learned from the assessment and intervention studies of the I-GENDO project were used to develop the guidelines for the use of digital technology proposed in Study 4 (Chapter 5). It was shown that the target group selection, content development and implementation of the EMA were successfully implemented in the I-GENDO project and are in line with the current literature. For future research, the experiences from Studies 1 to 3 show that in the further development of gender-sensitive intervention approaches, the participation of end-users in the development and evaluation phase should be expanded, the study design should be revised to make concrete statements about individualization and gender sensitivity, and human guidance during the intervention should be provided in order to increase engagement and effectiveness.

6.5 Limitations and Strengths

This dissertation presents some theoretical and methodological restrictions that offer starting points for future research. First, the I-GENDO intervention itself, and in particular the gender-sensitive tailoring feature (i.e., selection of female- or male-targeted variant), was not tested in a pilot study. In addition, there was no consistent implementation of UCD (McCurdie et al., 2012), which would have allowed the tailoring features to be tested with end-users during

the development phase. Second, the effectiveness of the I-GENDO intervention with regard to gender-sensitive research questions remain limited as the RCT was not designed to test gender-sensitivity in detail. The main limitation of Study 4 is the lack of control conditions that would have allowed to draw conclusions about the individualization and gender-sensitivity features of the app (Goldberg et al., 2023). We can conclude that the I-GENDO intervention is effective in changing eating behavior, but questions remain about the intervention effect with regard to BMI. In addition, as described in Chapter 1.2, BMI is a population measure that is regularly used in intervention studies, but has limited information about fat distribution and individual body composition. Therefore, future research should consider a greater variety of weight-based measures. Third, both within this dissertation and in the included original studies, sex/gender was treated as a binary demographic variable, and we dichotomously assessed male or female sex without assessing the broader spectrum of gender identities (Diethold et al., 2023; Hyde et al., 2019). Future studies should include more diverse subgroups and follow proposed guidelines for research with trans, gender diverse, and intersex individuals (B. Urban et al., 2024). Lastly, data collection for the EMA (Study 1) and intervention studies (Study 2 and Study 3) took place during the COVID-19 pandemic. Due to differences in the timing of study enrollment and assessment, it was not possible to systematically examine the potential influence of different restrictions (e.g., lockdown) in different parts of Germany that may have affected study conduct and results. This would be important because recent studies have observed changes in eating behavior, physical activity, and mental health in individuals with overweight and obesity during the pandemic (Melamed et al., 2022; Robinson et al., 2021).

This dissertation also has some noteworthy strengths. First, it combines a number of methodological approaches: multilevel model analysis, EMA, mHealth data, observational data, narrative review, RCT, longitudinal data. This comprehensive approach allowed the study and integration of health behaviors with emotional and cognitive processes, which is particularly important in the multimodal etiology and treatment of overweight and obesity. Second, gender- sensitivity as one potential aspect of individualization represents a promising and essential aspect of health behavior (M. Urban, 2021). The skill to develop and conduct gender-sensitive intervention and assessment studies will become more and more important to reduce health inequalities (Miani et al., 2021; Tannenbaum et al., 2019). The results of this dissertation provide a relevant basis for this and present a novel and innovative approach to the consideration of sex/gender in mHealth interventions. Further individualization features should be investigated in future studies to tailor interventions to subtypes of obesity, such as emotional

eating, restrained eating, as well as to sociodemographic aspects, such as age, comorbid physical or mental illnesses, and social inequalities (Cornejo Müller et al., 2020; Kohli et al., 2024; Szinay et al., 2023). Third, the I-GENDO intervention focused on modifying emotional and cognitive processes, which are increasingly important for improving patient self-efficacy and changing weight management behaviors. Emphasizing emotional and cognitive processes in the context of obesity treatment will remain important, especially with the increased use of pharmacological treatment (Fallows et al., 2023). In addition, it is important to incorporate more specific dietary and physical activity guidance to the psychological treatment and to integrate all treatment approaches into a holistic intervention. Fourth, this dissertation takes a comprehensive look at the various phases of planning, conducting, and evaluating assessment and intervention studies in the context of overweight and obesity. An important next step for the future is to examine implementation in real-world settings in more detail (Graham et al., 2020). The delivery and implementation of digital interventions in primary care remains a major challenge. Here, the introduction of DiHAs such as *zanadio* or *Oviva Direct für Adipositas* in Germany is a promising implementation option (Bretschneider & Schwarz, 2023).

6.6 Conclusion

The high prevalence of overweight and obesity worldwide and the corresponding low number of effective and sustainable treatment programs is a challenge. Ongoing advances in the development of mHealth interventions that can be used in everyday settings, have low barriers to access, and are cost-effective to disseminate, represent a promising approach to addressing this healthcare gap. While digital behavioral interventions have been shown to be effective in changing weight-related behaviors and weight in the short term, evidence of the sustainability and usability of these intervention effects is sparse. This dissertation contributes to filling these research gaps in the field of digital health in the context of overweight and obesity by providing a deeper understanding of how assessing individual associations between behavior and psychological processes, as well as individualized interventions, can improve acceptability, adherence, and intervention effectiveness. In particular, it provides evidence for the importance of emotional and cognitive processes and sex/gender as promising aspects of individualization to enhance long-term behavior change and successful weight loss management. The results presented enhance the understanding of how such psychological and individualized digital assessment and intervention approaches can be implemented in obesity healthcare. Overall, the findings of the four studies presented and discussed provide insights

into the development and evaluation of an individualized, gender-sensitive treatment approach, and how the development of future interventions in this area can be informed by the assessment of everyday behavior. The potential of digital approaches has been demonstrated in the four original studies included in this dissertation, but at the same time, the discussion offers starting points for expanding the field of research, such as integrating PPI, examining predictors of acceptance and adherence to digital solutions, and conducting long-term effectiveness analyses. Taken together, the evidence from the four studies can facilitate the development of holistic and targeted prevention and intervention approaches that harness the full potential of digital technology and make digital health more accessible and effective for people with overweight and obesity.

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Appendix

Zusammenfassung

Übergewicht und Adipositas sind mit einer Vielzahl von körperlichen und psychischen Folgen assoziiert. Der damit verbundene Verlust an Lebensqualität kann Menschen mit Übergewicht dazu motivieren, an Gewichtsreduktionsmaßnahmen teilzunehmen. Forschungsergebnisse zeigen, dass die Teilnahme an einem behavioralen Gewichtsreduktionsprogramm das Ernährungs- und Bewegungsverhalten erfolgreich beeinflusst und zu einer Gewichtsabnahme führen kann. Allerdings ist die Verhaltensänderung oft nicht nachhaltig, was zu ungünstigen emotionalen Erfahrungen und erneuter Gewichtszunahme führen kann. Darüber hinaus besteht trotz der weltweit steigenden Prävalenz von Übergewicht und Adipositas ein Mangel an adäquaten und nachhaltigen Behandlungsmöglichkeiten. Diese Versorgungslücke kann durch die Entwicklung und den Einsatz neuartiger digitaler Assessment- und Interventionsansätze, die der Komplexität von Übergewicht und Adipositas Rechnung tragen, geschlossen werden. Mobile Gesundheitsinterventionen (mHealth), die über Smartphone-Apps bereitgestellt werden, sind hierfür besonders geeignet, da sie das Gesundheitsverhalten direkt im Alltag beeinflussen können und einen niedrigschwelligen Zugang bieten. Allerdings sind auch mHealth-Interventionen nur kurzfristig wirksam. Für die Behandlung von Übergewicht und Adipositas werden Interventionsansätze benötigt, die eine nachhaltige Verhaltensänderung ermöglichen.

Das Ziel dieser Dissertation ist es, 1) einen Überblick über die aktuelle Evidenz und Wirksamkeit von (digitalen) Interventionen zur Gewichtsreduktion darzustellen und 2) zwei vielversprechende Ansätze vorzustellen, die die langfristige Wirksamkeit von Interventionen erhöhen könnten: Erstens die Integration von zugrundeliegenden emotionalen und kognitiven Faktoren in Assessment- und Interventionsstudien und zweitens die Berücksichtigung von Geschlecht/Gender als Individualisierungsansatz in mHealth. Der Hauptteil dieser Arbeit besteht aus vier Originalstudien, die jeweils zu diesen beiden Zielen beitragen.

Studie 1 untersuchte den bidirektionalen Zusammenhang zwischen Affekt und täglicher körperlicher Aktivität im Rahmen einer 7-tägigen Ecological Momentary Assessment (EMA)-Studie. Bisher fehlen Studien, die den Zusammenhang zwischen Affekt (d.h. Valenz, Arousal. Ruhe) und körperlicher Aktivität bei Personen mit Übergewicht und Adipositas untersuchen.

Für die EMA-Studie wurden Daten von 157 Teilnehmenden (Body-Mass-Index, BMI: 32,99 ± 3,87 kg/m^2) in eine Mehrebenen-Modellanalyse einbezogen. Die Teilnehmenden trugen an sieben aufeinander folgenden Tagen einen Beschleunigungsmesser und füllten EMA-Fragebögen aus. Die Ergebnisse zeigten einen signifikanten bidirektionalen Zusammenhang zwischen körperlicher Aktivität und Arousal und Ruhe, jedoch nicht für Valenz. Dies deutet darauf hin, dass sich die affektsteigernde Reaktion auf körperliche Aktivität von den Erfahrungen von Personen mit einem BMI unter 25 unterscheidet. Bei der Entwicklung von mHealth-Interventionen sollte darauf geachtet werden, realistische Erwartungen bezüglich der Auswirkungen von körperlicher Aktivität auf den Affekt zu kommunizieren und die Facetten des Affekts durch Interventionen zu modifizieren.

In Studie 2 wurden der Entwicklungsprozess, die Benutzerfreundlichkeit und die Akzeptanz der individualisierten, gendersensiblen mHealth-Intervention I-GENDO präsentiert. Die selbstgeleitete I-GENDO Intervention wurde entwickelt, um kognitive und emotionale Aspekte im Zusammenhang mit Gewicht und gewichtsbezogenem Verhalten zu verändern. Kognitiv-verhaltenstherapeutische Behandlungsstrategien wurden in zwei geschlechtssensiblen Varianten zur Verfügung gestellt. Die Analyse der Nutzungsmuster von 116 Teilnehmenden (BMI: 33,07 kg/m^2), die die I-GENDO-Intervention über einen Zeitraum von 12 Wochen nutzten, ergab, dass die App von weiblichen Teilnehmerinnen durchschnittlich 625 Minuten und von männlichen Teilnehmern 347 Minuten genutzt wurde und dass die Gesamtnutzungszeit im Verlauf der Intervention abnahm. Signifikante geschlechtsspezifische Unterschiede wurden bei der Nutzung der App festgestellt, jedoch nicht bei der Bewertung von Akzeptanz, Benutzerfreundlichkeit und Zufriedenheit. Der innovative gendersensible Interventionsansatz wurde erfolgreich implementiert, jedoch sind weitere Untersuchungen notwendig, um die Motivation der weiblichen und männlichen Nutzer zu verstehen, sich für eine bestimmte Behandlungsvariante zu entscheiden.

In Studie 3 wurde untersucht, ob die Nutzung der 12-wöchigen gendersensiblen mHealth-Intervention I-GENDO das gewichtsbezogene Verhalten (d.h. Ess- und Bewegungsverhalten) und das Gewicht (d.h. BMI) bei Frauen und Männern verändert. Die Studie präsentiert die Ergebnisse einer randomisiert kontrollierten Studie (RCT), an der 116 Teilnehmende in der Interventionsgruppe und 97 Frauen und Männer in der Kontrollgruppe (BMI: 33,58 kg/m^2) teilnahmen. Durch die Bearbeitung der zugrundeliegenden kognitiven und emotionalen Aspekte von Übergewicht und Adipositas mit der I-GENDO-Intervention konnten Verbesserungen des Essverhaltens und eine Reduktion des BMI erreicht werden. Die

Interventionseffekte waren jedoch hinsichtlich ihrer Nachhaltigkeit uneinheitlich und es zeigten sich signifikante Geschlechtsunterschiede in den Interventionseffekten. Die Ergebnisse bestätigen, dass insbesondere kognitive Aspekte durch die selbstgeleitete mHealth-Intervention verändert werden können. Die Aussagekraft der Ergebnisse bleibt jedoch eingeschränkt, vor allem, weil das gewählte Studiendesign keine konkreten Aussagen zur Wirksamkeit des neuartigen gendersensiblen Ansatzes und der Individualisierungsmerkmale zulässt.

In Studie 4 werden Empfehlungen für Forschende im Bereich digitaler Technologien zur Entwicklung, Evaluation und Implementierung von mHealth vorgeschlagen. Die Ergebnisse der I-GENDO Assessment- und Interventionsstudien flossen in die Entwicklung dieser Empfehlungen ebenso ein wie aktuelle Literatur. Die Empfehlungen wurden mittels eines adaptierten Delphi-Verfahrens von 25 Autorinnen und Autoren mit einschlägiger Expertise im Bereich der digitalen psychischen Gesundheit entwickelt und decken Themen wie die Entwicklung von Interventionsinhalten, nutzerzentriertes Design, partizipative Ansätze, Datenschutz, künstliche Intelligenz, Sensoren und Wearables, Wirksamkeitsbewertung und den Transfer in die klinische Praxis ab. Der Schwerpunkt liegt dabei auf der Notwendigkeit praktikabler und langfristiger Erhebungsmethoden.

Zusammenfassend unterstreichen die Ergebnisse dieser Dissertation die Bedeutung kognitiver und emotionaler Prozesse als zugrundeliegende Faktoren für eine langfristig erfolgreiche Gewichtsreduktion und Verhaltensänderung im Alltag, die die Entwicklung individualisierter mHealth-Interventionen beeinflussen können. Die Ergebnisse der vorgestellten Studien liefern wichtige neue Erkenntnisse darüber, wie kognitive und emotionale Mechanismen, die das Gesundheitsverhalten beeinflussen, in einem gendersensiblen Behandlungsansatz für die digitale Adipositas-Therapie umgesetzt werden können. Gleichzeitig werden aber auch Limitationen aufgezeigt und zukünftige Richtungen für die Entwicklung und Evaluation individualisierter psychologischer Interventionen diskutiert, wie z.B. die stärkere Einbindung von Nutzerinnen und Nutzern in die Entwicklung von mHealth-Ansätzen und die Erhöhung der Adhärenz.

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