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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

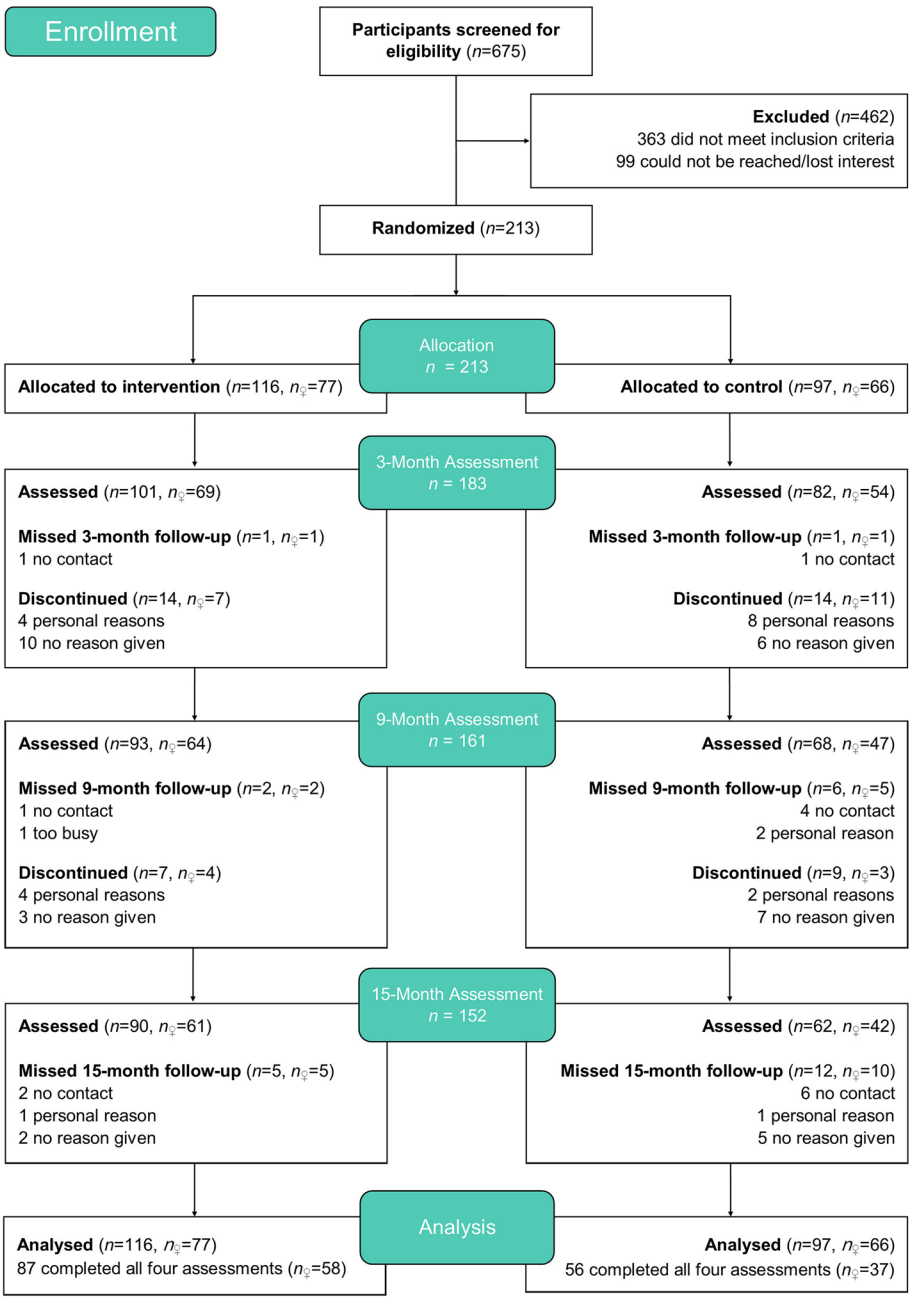

Fig. 1 CONSORT flow diagram of the randomized controlled trial. *Note.* *n* = indicates the total number of participants included/excluded in the respective group at the respective point in time; *n*♀ = indicates the total number of female participants included/excluded in the respective group at the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

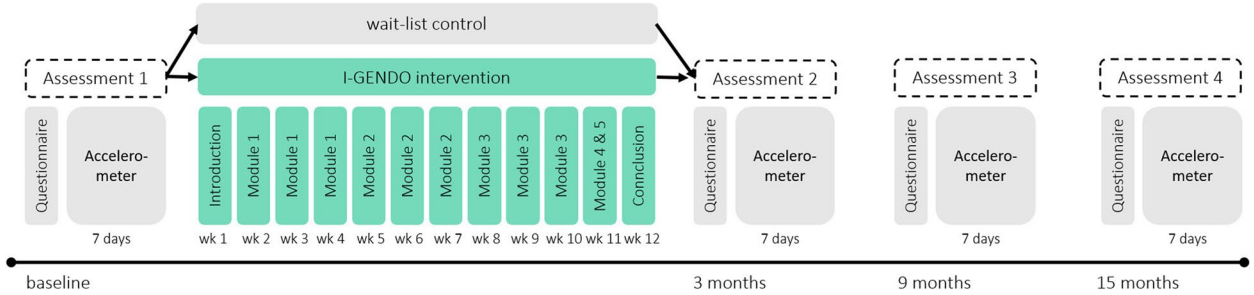

Fig. 2 Intervention procedure and assessments

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

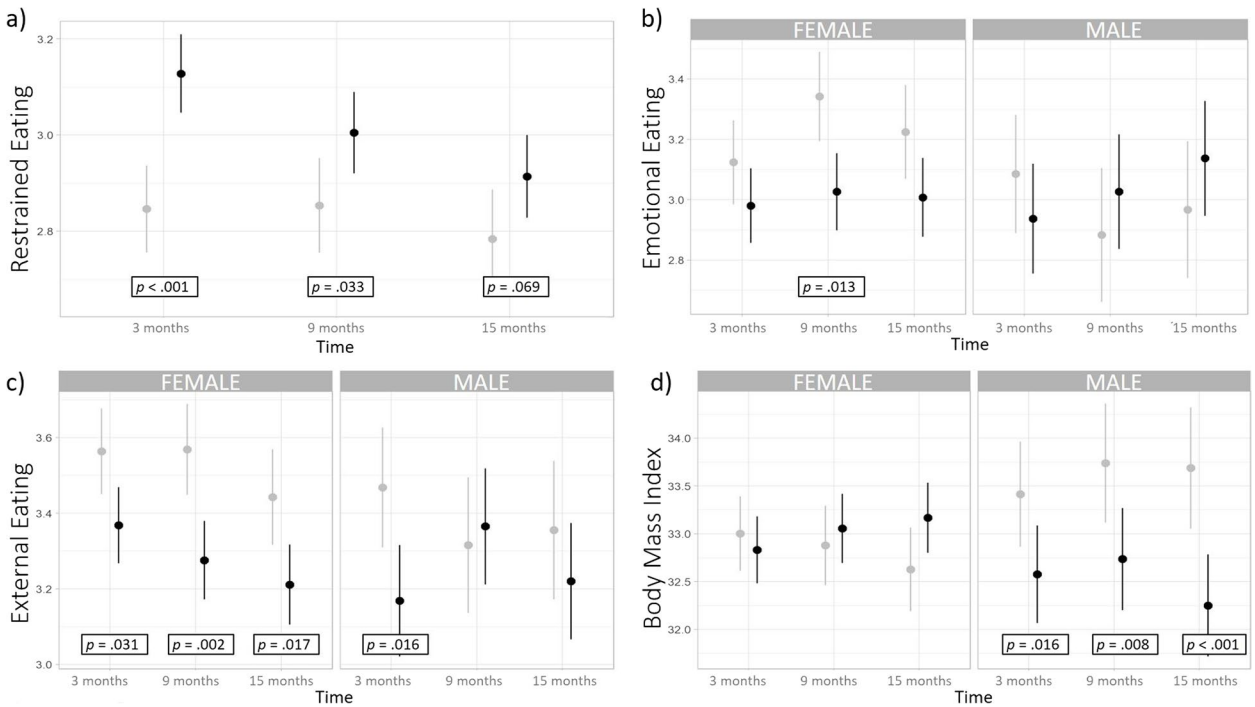

Fig. 3 Intervention effect for each outcome at each assessment. *Note.* Between-group differences (black = intervention group, gray = control group) adjusted for baseline value for **a**) restrained eating, **b**) emotional eating, **c**) external eating, **d**) BMI at each assessment for each gender. 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.

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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

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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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