Well-Being Therapy and Lifestyle Intervention in Type 2 Diabetes: A Pilot Randomized Controlled Trial

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Total number of words: 6247
Number of tables: 1
Number of figures: 2

Running title: Well-being and Lifestyle in Diabetes

Conflicts of Interest and Source of Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Authors have no conflicts of interest to declare.

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Abstract

Objective: This pilot randomized controlled trial evaluates the preliminary efficacy of a 4-month Well-Being Therapy (WBT)~~well-being~~ and lifestyle intervention ~~(WBT-lifestyle)~~ among adults with type 2 diabetes and overweight/obesity.

Methods: Fifty-eight patients were recruited from two outpatient clinics and randomized to receive the WBT-lifestyle intervention or the lifestyle intervention alone. Data were collected at baseline (T0), immediate post-intervention (T1), 6-month follow-up (T2), and 12-month follow-up (T3). Primary efficacy outcomes included changes in weight, psychological distress, and well-being, while secondary efficacy outcomes included changes in lifestyle and physiological parameters.

Results: Compared to the lifestyle-alone intervention, the WBT-lifestyle intervention showed greater improvements in depression (p = 0.009, d = -0.6), hostility (p = 0.018, d = -0.6), and personal growth (p = 0.026, d = 0.5) at T1, in self-reported physical activity at T2 (p = 0.013, d = 0.7) and T3 (p = 0.040, d = 0.5), and in triglycerides (p = 0.019, d = -1.12) at T3. There were no differences between treatment groups in weight and other physiological parameters.

Conclusions: These findings suggest that ~~a~~ Well-Being Therapy~~well-being approach~~ may be a valuable addition to lifestyle interventions for improving short-term psychological outcomes and promoting long-term healthy changes in physical activity, with a potential impact on physiological outcomes.

Trial Registration: NCT03609463 https://clinicaltrials.gov

Key words: type 2 diabetes; obesity; Well-Being Therapy; euthymia;~~well-being; distress;~~ lifestyle

1. Introduction

Several psychosocial factors have been found to have an impact on individual vulnerability, course, and outcome of medical disease, and to influence disease management by interfering with behavioral change (1). Specifically, psychological distress is common among patients with type 2 diabetes (2,3) and has been linked to poor health behaviors and adverse clinical outcomes (4). On the other hand, various indicators of psychological well-being have been associated with better health outcomes across numerous medical conditions (5). In line with these findings, the American Diabetes Association has recently acknowledged the role of psychosocial factors in diabetes (6).

Psychological interventions for the promotion of well-being have shown some promising findings in reducing levels of distress and improving health-related outcomes among patients with chronic medical conditions like diabetes (7). However, only a few studies are available on this topic and the data are still preliminary, which highlights the need for investigating novel methods of enhancing well-being and other psychological parameters to improve physiological health outcomes (7).

Well-being therapy (WBT) (8) is a manualized, short-term psychotherapeutic strategy for the promotion of psychological well-being, according to Jahoda's conceptual framework (9). In line with this framework, positive mental health is characterized by distinct dimensions of psychological well-being, including autonomy, environmental mastery, positive relations with others, purpose in life, personal growth, and self-acceptance. Unlike many well-being interventions, WBT is not aimed at maximizing positive emotions and cognitions but rather at achieving a state of euthymia or optimal balance among different areas of psychological well-being (10). While the term euthymia is commonly used in psychiatry to refer to a patient who no longer meets the threshold for a disorder like depression or mania, euthymia here aligns with the definition proposed by Fava and Bech (11). According to this definition, euthymia is a state of emotional and cognitive flexibility, consistency, and resilience resulting in the presence of positive affect and psychological well-being, in the context of a lack of

mood disturbances and temporary, minimal distress. A similar concept of euthymia, as a state of positive mental health and psychological well-being, has also been proposed as a key target for diabetes care (12). Within the concept of euthymia used in the present study, it is also recognized that both impaired and excessive levels in dimensions of psychological well-being can occur and result in suboptimal functioning (10).

WBT has been effective in increasing levels of recovery in depression and generalized anxiety disorder, modulating mood in cyclothymic disorder, and promoting mechanisms of resilience and psychological well-being in an educational setting (10). In the medical setting, the sequential combination of Cognitive Behavioral Therapy (CBT) and WBT has been applied to patients with acute coronary syndrome and depression and/or demoralization, leading to significant improvements in depressive symptoms and biomarkers of cardiovascular health (13). These findings suggest the potential role of WBT in managing the challenges related to chronic medical conditions and in promoting healthy behaviors (10). Even if lifestyle interventions are considered a first-line intervention for the management of obesity and diabetes, they often focus on diet and physical activity, and neglect the role of psychological distress and its negative impact on behavioral change. Not only may the presence of well-being lead to a reduction in distress (14), but its presence has also shown to have a buffering effect in protecting against the negative effects of distress on health and health behaviors (15). This led us to hypothesize that the addition of an intervention for the promotion of psychological well-being to a lifestyle intervention could promote healthy lifestyle changes by reducing distress, leading to greater improvements than a lifestyle intervention alone.

The main aim of this pilot study was to evaluate the feasibility, acceptability, and preliminary efficacy of a 4-month combined well-being and lifestyle (WBT-lifestyle) intervention in patients with type 2 diabetes, compared to a lifestyle intervention alone (lifestyle-alone) at immediate post-intervention, 6-month follow-up, and 12-month follow-up. The WBT-lifestyle intervention was expected to result in greater improvement in weight, psychological distress, and psychological well-being (primary efficacy outcomes); and in lifestyle and physiological parameters (secondary efficacy outcomes).

2. Materials and Methods

2.1. Study design and participants

This pilot study is a two-center, parallel-arm, assessor-blinded, randomized controlled trial. Participants were recruited from March 2018 to June 2019 at two outpatient endocrinology clinics in northern Italy (*Bufalini Hospital* in Cesena and *Oglio Po Hospital* in Cremona).

Physicians and nurses at both sites were given a brief checklist of main eligibility criteria and were asked to screen consecutive patients attending the clinic during the enrollment period. Patients who appeared eligible were introduced to the study and referred to one of the study researchers, who scheduled an in-person meeting at the clinic for an in-depth screening evaluation. Eligibility was determined based on medical chart review and patients' self-reported information using an ad hoc checklist.

Participants were eligible if they a) were overweight or obese (BMI $\geq$ 25), b) adult (18-65 years old), and c) had a diagnosis of type 2 diabetes. Reasons for exclusion included a) inability to speak Italian fluently, b) inability to provide informed consent, c) medical conditions that could interfere with study participation or associated with unintentional weight change (i.e., any cancer, congestive heart failure, untreated or unstable hyperthyroidism, kidney failure on dialysis, and severe orthopedic disorders); d) untreated, severe, or recently diagnosed ($\leq$ 6 months) mental illness or personality disorder, e) history of eating disorders or substance abuse, f) use of appetite suppressants, lipase inhibitors, and dietetic products, g) involvement in another behavioral intervention, h) history of weight loss surgery or weight loss surgery scheduled within the next year, i) pregnancy or intention to become pregnant within the next year, and l) inability to control meal contents (e.g., institutionalized patients).

Eligible participants were randomized to either the WBT-lifestyle intervention or the lifestyle-alone intervention with an allocation ratio of 1:1. The possibility of being randomized to one of two different interventions was made clear to participants during the consent process. The randomization schedule was generated using *Random Allocation Software 2.0*. Block randomization with random block sizes was used to

ensure a balance in sample size across groups while maintaining the unpredictability of the randomization process.

Data were collected by review of medical charts, anthropometric measures of weight, and Patient-Reported Outcome Scales (PROMs) at baseline (T0), post-intervention (T1), 6-month follow-up (T2), and 12-month follow-up (T3). Study researchers responsible for data collection were graduate students in clinical psychology. Weight was assessed in person, using a standard balance beam scale at each clinic. Questionnaires were provided in paper-pencil format and participants were asked to complete all questionnaires at home and return them completed within one week. Upon return, the study researcher checked the questionnaires for completeness and discussed any unfilled entries with the study participant. Six participants, three in the WBT-lifestyle intervention group and three in the lifestyle-alone intervention, had their 6-month follow-up assessment scheduled between March and May 2020, and 20 participants, 10 in the WBT-lifestyle intervention group and 10 in the lifestyle-alone intervention, had their 12-month follow-up assessment scheduled between March and November 2020. Since this period corresponded to the time of mandatory quarantine due to the spread of COVID-19, questionnaires were delivered over the phone and measures of weight were self-reported for these participants, with instructions to use their own standard digital scale to weigh themselves at home in the morning, wearing light clothing, after voiding, and to submit a picture of the measurement on the scale.

The trial received approval from the Ethics Committee of each clinic, the *Comitato Etico della Romagna* and the *Comitato Etico Val Padana*. Study procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association. The study was registered on ClinicalTrials.gov (**NCT03609463**). All study participants provided written informed consent.

2.2. Procedures

Participants were involved in the study intervention for up to four months. During the first four weeks, participants in the WBT-lifestyle group received the well-being intervention in combination with treatment as usual, while those in the lifestyle-alone group were asked to continue their treatment as usual only. In the following 12 weeks, participants in both groups received the same lifestyle intervention, including in-person and phone meetings, in combination with treatment as usual. Although WBT was delivered before the start of the lifestyle intervention, monitoring of well-being experiences and activities continued during the lifestyle intervention for those in the WBT-lifestyle group. We adopted this format to allow participants in the combined group to become familiar with this new approach, and learn techniques related to their well-being to help motivate lifestyle change during the lifestyle-alone period.

The same clinical psychologist (G.B.) provided the intervention in both groups in one-to-one sessions with each participant. Two psychotherapists with expertise in WBT (G.A.F. and C.R.) offered supervision for the implementation of the well-being intervention for the entire duration of the study.

Below is a description of the protocol for each intervention. A detailed description of the WBT-lifestyle intervention has been published elsewhere (16).

2.2.1. Well-being intervention protocol

The well-being intervention was adapted from the WBT protocol (8) and delivered in four individual, weekly sessions. Each session lasted for about an hour and was conducted in-person in a private room at each clinic.

The intervention was characterized by the following features: a) participants were encouraged to identify episodes of well-being that recently occurred and to set them in a situational context with the use of a structured diary; b) once the instances of well-being were recognized, the participant learned to identify thoughts and/or behaviors leading to premature interruption of well-being, as is performed in CBT; c) homework assignments

that elicit psychological well-being and, particularly, optimal experiences were prescribed; d) monitoring of the diary allowed to discover specific impairments or, conversely, excessive levels of well-being dimensions according to Jahoda's conceptual framework (9); e) participants were not simply encouraged to pursue the highest possible levels of psychological well-being, but to obtain an optimal balanced functioning, i.e., euthymia (17). The participant thus became able to readily identify moments of well-being, to be aware of interruptions to well-being feelings (interfering thoughts and/or behaviors), and to apply cognitive behavioral techniques to address these interruptions and pursue optimal experiences (see Data, Supplemental Digital Content Table S1 for a session-by-session description of the intervention).

2.2.2. Lifestyle intervention protocol

The lifestyle intervention was delivered in 12 individual weekly sessions. Four sessions (i.e., session number 1, 4, 8, and 12) were conducted in-person in a private room at each clinic and lasted for about an hour, while the remaining sessions were conducted over the phone and lasted for about 30 minutes.

The intervention has been modeled after the Small Changes and Lasting Effects (SCALE) trial protocol (18), and developed in the context of the Small Changes Approach (19) and the Social Cognitive Theory (20). Specifically, it assumes that small changes in diet and physical activity, being more feasible to achieve and maintain, may increase feelings of self-efficacy, stimulate additional changes, and result in gradual weight loss over time.

The objective of the lifestyle intervention was therefore to help participants gradually lose weight by making small changes in their lifestyle. The intervention included three key components: monitoring of lifestyle changes and weight, goal setting, and problem solving (see Data, Supplemental Digital Content Table S1).

2.2.3. Treatment as usual

All participants received medications for diabetes and health-related comorbidities and, whenever

necessary, their physician gave them instructions on how to self-monitor their glycemic level. At both clinics, participants attended regular follow-up visits with their physician.

2.3. Feasibility and acceptability outcomes

The study feasibility and acceptability were assessed as eligibility rate (i.e., total number of patients eligible out of the total number of patients approached), acceptance rate (i.e., total number of participants enrolled out of the total number of eligible patients), and retention rate (i.e., total number of participants who completed the study out of the total number enrolled). Participants' satisfaction and suggestions for improvement were also assessed at the end of the intervention by asking the following open-ended questions: "Which component of the study did you find to be the most useful?" and "Do you have any suggestions on how to improve the study?".

2.4. Primary efficacy outcomes

Body weight was measured in kilograms on a standard balance beam scale at each clinic or on a standard digital scale at participants' home, as described above.

Psychological distress was assessed using the Italian version (21) of the Symptom Questionnaire (SQ) (22,23), a 92-item self-rating questionnaire for the assessment of four main scales: anxiety, depression, hostility, and somatization. Each scale includes items indicating the presence of symptoms and others indicating the presence of well-being. For example, the anxiety scale includes items like "Nervous" and "Relaxed". Answers to each item are dichotomous, and each scale can be scored separately, with higher scores indicating higher levels of psychological symptoms.

The presence of stress was assessed using the stress scale of the Italian version of the Psychosocial Index (PSI) (24,25). This scale has been used extensively for a clinimetric definition of allostatic overload (26,27) and includes 17 items for the assessment of both perceived and objective stress, life events, and chronic stress. Eight

items ask about the occurrence of specific events in the past year (e.g., “Financial difficulties”), and the other nine items ask about current situations and perceptions (e.g., “Do you feel under pressure during the day?”). Answers to each item are dichotomous, with higher scores indicating higher stress.

Psychological well-being was assessed using the Italian version (28) of the Psychological Well-Being Scales (PWBs) (29), a 42-item self-rating questionnaire for the assessment of six scales: autonomy (e.g., “I tend to be influenced by people with strong opinions”), environmental mastery (e.g., “I often feel overwhelmed by my responsibilities”), personal growth (e.g., “When I think about it, I haven’t really improved much as a person over the years”), purpose in life (e.g., “I don’t have a good sense of what it is I’m trying to accomplish in life”), self-acceptance (e.g., “In many ways I feel disappointed about my achievements in life”), and positive relations with others (e.g., “Maintaining close relationships has been difficult and frustrating for me”). Respondents are asked to rate the extent to which they agree with each item on a six-point Likert scale. Each scale can be rated separately, with higher scores indicating higher levels in psychological well-being.

2.5. Secondary efficacy outcomes

Lifestyle changes were assessed using the Mediterranean diet, dietary behavior, and physical activity scales of the GOSPEL questionnaire (30). The Mediterranean diet scale includes 10 items that assess the frequency of consumption of specific foods and beverages (e.g., fruit, fish). Each item is scored on a four-point Likert scale and can be summed to obtain a Mediterranean diet score, with higher scores indicating better adherence to the Mediterranean diet. The dietary behavior scale includes three items that assess the frequency of certain eating behaviors (e.g., “eating regularly”). Each item is scored on a four-point Likert scale and can be summed to obtain an eating habit score, with higher scores indicating better eating habits. The physical activity scale includes five items that assess the frequency of specific types of physical activity (e.g., walking) on a four-point Likert scale, two items that assess engagement in sports on a dichotomous scale, and one item that assesses

the overall self-perceived level of physical activity on a four-point Likert scale. Scores on each item can be summed to obtain a total physical activity score, with higher scores indicating higher levels of physical activity.

Eating behaviors were assessed using the Italian version (31) of the Dutch Eating Behavior Questionnaire (DEBQ) (32), a 33-item self-rating questionnaire for the assessment of three scales: restrained eating (e.g., "Do you watch exactly what you eat?"), emotional eating (e.g., "Do you have the desire to eat when you are feeling lonely?"), and external eating (e.g., "If food smells and looks good, do you eat more than usual?"). Answers to each item are given on a five-point Likert and each scale can be scored separately, with higher scores indicating greater endorsement of the eating behavior.

Finally, physiological parameters, including hemoglobin A1c (HbA1c, %), HDL cholesterol (mg/dL), LDL cholesterol (mg/dL), triglycerides (mg/dL), and blood pressure (mmHg), were collected from medical charts for each participant.

2.6. Statistical methods

The sample size was estimated a priori using G*Power 3.1. Previous studies have shown a moderate effect size of psycho-behavioral interventions on weight loss and measures of depression and anxiety in adults with overweight or obesity (33). To detect a medium effect size (d = 0.15) at the statistical power of 0.80, a minimum of 34 participants is required. Considering a risk of drop-out of about 50% (34), 68 participants were intended to be recruited. Because this trial is a pilot and not intended to be confirmatory, adjustment for multiple comparisons was not planned (35).

Baseline differences between intervention groups were analyzed by means of Pearson's chi-squared test for categorical variables, independent samples Student's t-test for normally distributed continuous variables, and Mann–Whitney *U* test for non-normally distributed continuous variables.

Main analyses on feasibility and acceptability were descriptive and focused on rates. Primary and secondary efficacy outcomes were assessed with linear mixed-effects modeling to estimate adjusted mean

treatment difference and confidence intervals according to intention-to-treat (ITT) principles. Age, sex, completion of high school education, site, and group by time interaction were included as fixed effects, and participant ID as a random effect, to analyze changes between and within-groups over time. Differences between groups in outcome measures at baseline were accounted for by using a constrained longitudinal data analysis. Residual histograms of the efficacy outcomes were assessed visually and considered to be sufficiently normally distributed, and plots of the fitted values against the standardized residuals of the efficacy outcomes were assessed visually to confirm homoscedasticity.

Between and within-group effect size estimates were reported as Cohen's d calculated as adjusted mean difference between groups divided by pooled between-group baseline standard deviation and as predicted mean change from baseline divided by the pooled within-group standard deviation at baseline and T1, T2, or T3, respectively.

Statistical analyses were conducted in Stata/SE, version 16.1 (StataCorp 2019, College Station, TX, USA). Statistical significance was set at $p \leq 0.05$, two-tailed, with 95% confidence intervals reported.

3. Results

3.1. Feasibility and acceptability

Fifty-eight participants were enrolled in the study (**Figure 1**). Most of the patients attending the two clinics during the time of enrollment were not eligible because they were older than 65 years (74%). Among eligible patients, 24% consented to participate. The main reasons for refusal were lack of time due to work (41%) and family obligations (20%). Of those who were enrolled in the study, 74%, 71%, and 62% completed the T1, T2, and T3 assessment, respectively. Due to a lower drop-out rate than anticipated, we did not deem it necessary to reach the target of 68 participants enrolled.

When asked which component of the study they found to be the most useful, participants often mentioned receiving psychological support (30%), being given information on how to improve their lifestyle (26%), and having regular meetings (20%). Common suggestions for improvement included having group sessions to share the experience with other participants (27%), including additional follow-up sessions after the end of the intervention (18%), and replacing some of the phone calls with more face-to-face meetings (18%).

Baseline demographics and clinical characteristics of the sample are presented in **Table 1**.

3.2. Primary Efficacy Outcomes

3.2.1. Psychological distress and well-being

Participants in the WBT-lifestyle group experienced significantly greater improvements in levels of depression (adjusted mean difference (AMD) = -2.1, $p = 0.009$, d = -0.6), hostility (AMD = -2.5, $p = 0.018$, d = -0.6), and personal growth (AMD = 3.3, $p = 0.026$, d = 0.5) at T1, compared with the lifestyle-alone group. However, between-group differences were no longer significant at T2 and T3 (**Figure 2**; see Data, Supplemental Digital Content Tables S2, which show observed means and adjusted between-group differences).

No differences between groups were observed for other measures of psychological distress and well-being at any assessment point.

3.2.2. Weight

No between-group differences in weight loss were observed at any assessment point, with a statistically significant but negligible within-group decrease in weight in both treatment groups at T1 and T2 (**Figure 2**; see Data, Supplemental Digital Content Table S2 and Table S3, which show observed means and adjusted within-group change over time).

3.3. Secondary Efficacy Outcomes

3.3.1. Lifestyle

While at T1 there were no differences between treatment groups in levels of physical activity, at T2 (AMD = 1.9, $p = 0.013$, d = 0.7) and T3 (AMD = 1.6, $p = 0.040$, d = 0.5) there was a greater increase in the WBT-lifestyle group compared to the lifestyle-alone group (**Figure 2**; see Data, Supplemental Digital Content Table S2**)**.

No significant between-group differences were observed in any of the diet measures considered at any assessment point.

3.3.2. Physiological parameters

While at T1 and T2 there were no differences between treatment groups in any of the physiological parameters, at T3 there was a greater decrease in levels of triglycerides (AMD = -142.6, $p = 0.019$, d = -1.12) in the WBT-lifestyle group compared to the lifestyle-alone group (**Figure 2**; see Data, Supplemental Digital Content Table S2**)**.

No significant between-group differences were observed in any of the other physiological parameters considered at any assessment point.

4. Discussion

This is the first study to evaluate the preliminary efficacy of combining a psychological well-being intervention based on WBT (8) with a lifestyle intervention in a clinical setting among outpatients with type 2 diabetes and overweight or obesity.

The study was found to be both feasible and acceptable, with a retention rate of about 70% after 10 months from the beginning of the intervention. Low rates of retention are one the major challenges in the

treatment of obesity, with observed retention rates as low as 20% (34). Despite these promising results, only 24% of eligible patients accepted to participate in the study. A common barrier to both study enrollment and retention was lack of time due to family and work constraints. A potential solution to this is transitioning to remote intervention procedures. Previous studies utilizing remote interventions with participants in various medical and non-medical settings have reported excellent feasibility and acceptability rates (36).

Our findings indicate that combining WBT with a lifestyle intervention may bring significantly greater improvements in both psychological distress (depression and hostility) and well-being (personal growth) at immediate post-intervention compared to implementing a lifestyle intervention alone. It is increasingly recognized that the relationship between well-being and distress is complex, being independent but inter-related dimensions (14). Therefore, our findings may reflect the impact of WBT on distress through the mediating effect of improved well-being and movement toward a more euthymic state. The superiority of the WBT-lifestyle intervention was not maintained at follow-ups, as improvements in distress were also seen in the group receiving the lifestyle-alone intervention over the course of the study. This is not surprising, as it has previously been observed that lifestyle interventions for weight loss can improve psychological health in patients with type 2 diabetes and obesity even without a psychological component (37). Moreover, at the 6-month follow-up, levels of personal growth started to decrease in the WBT-lifestyle intervention. The PWB scales used in this study capture only some elements of euthymia, and not flexibility, consistency, resilience, or excessive levels of well-being dimensions. It is possible that assessments specifically focused on measuring euthymia, such as the Euthymia Scale (11, 38) and the Clinical Interview for Euthymia (10), would have been more sensitive for capturing change.

Participants in both treatment groups experienced a statistically significant weight loss from baseline to post-intervention that was sustained at follow-ups. However, effect sizes were negligible in both treatment groups. A statistically significant and sustained weight loss has been reported in previous studies using the small changes approach, none of which focused exclusively on patients with diabetes (39,40). An exploratory post hoc

analysis by Lutes et al. (40) suggested that participants with diabetes experienced worse weight loss outcomes during a small changes intervention compared to those without diabetes, possibly related to higher baseline levels of distress, which may explain the negative results of our study.

The WBT-lifestyle intervention showed a sustained and moderate effect in promoting self-reported physical activity compared to the lifestyle-alone intervention. This is a promising finding since, even when not associated with clinically significant weight loss, an increase in physical activity can have several health benefits in patients with diabetes (41). Recent studies have also found a significant association between increased physical activity and improvements in psychological distress and well-being, including measures of personal growth (42). In our study, the PWB scale of personal growth encompasses items reflecting a person's sense of improvement and motivation in making changes in their life (29). The observed initial improvements in the dimension of personal growth may therefore indicate an improvement in levels of motivation that could explain the greater changes in physical activity observed in the WBT-lifestyle intervention.

Finally, greater improvements in levels of triglycerides were observed at 12-month follow-up in the group receiving the WBT-lifestyle intervention, with no differences between groups in any of the other physiological parameters considered. Mixed results are available in the literature, with some studies indicating a small or no effect on glycemic control from psychological interventions to reduce distress in patients with diabetes and others where better psychological outcomes and increased physical activity were associated with improved glycemic control (43,44). However, our study was not powered to detect a significant difference between groups in physiological parameters, and our positive findings should be interpreted with caution as physiological data at follow-ups were available for only a minority of the initial study sample.

Our findings need to be considered within the context of study limitations. First, there was only a limited number of WBT sessions (four) compared to the eight suggested in the manual (8). It is possible that a more extended use of WBT, with booster sessions during the follow-up, might have yielded more pronounced and enduring gains. Second, we chose to exclude patients older than 65 years of age due to possible risks associated

with weight loss in older adults (45). Moreover, older adults with diabetes may have more medical complications, and we hoped that limiting our recruitment to younger patients would result in a more homogeneous sample. However, the prevalence of diabetes increases with age (46), and this may limit the generalizability of our findings. Third, the same clinical psychologist delivered both interventions and, due to the nature of the intervention, neither the clinical psychologist nor the participants were blinded to allocation. To reduce potential bias the clinical psychologist was asked to follow a strict pre-specified intervention protocol and both the assessors and the statistician were blinded to treatment allocation. Fourth, while self-reported questionnaires are important to collect information on PROMs (47), the use of observer-rated methods would have yielded a more comprehensive evaluation. As to perceived levels of physical activity, the additional use of objective measures, such as those provided by accelerometers, could have complemented our data and led to a more precise estimate (48). Moreover, due to their subjective nature, self-reported measures may be impacted by social desirability bias so future studies should make every effort to incorporate objective physical activity measures to corroborate subjective instruments. Fifth, a number of participants had their 6-month and 12-month follow-up assessment during COVID-19 and this may have had an impact on their mental state and lifestyle habits. However, an equal number of participants in each treatment group had their assessments during COVID-19 and we do not believe this impacted the results. Finally, as this was a pilot trial, no adjustment for multiple comparisons was made (35), so the findings should be interpreted as preliminary.

5. Conclusions

The results of this study show preliminary evidence that a combined well-being and lifestyle intervention can be feasible and acceptable in the setting of an outpatient diabetes clinic, and that a well-being component aimed at reaching a state of euthymia may be a useful addition to a lifestyle intervention in improving psychological outcomes and promoting healthy changes. Lifestyle modification focused on weight reduction,

increased physical activity, and dietary change is advised as first-line therapy in several disorders, yet psychological distress and low levels of well-being are commonly observed among patients with chronic conditions and represent important obstacles to behavioral change. It has been argued that enduring lifestyle changes can only be achieved with a personalized approach that targets psychological well-being. The results of this pilot trial offer novel psychological strategies incorporating euthymia into interventions for obesity and diabetes care.

Supplemental Digital Content.docx

Acknowledgements

We thank Alexandra Popa Paula, Donata Azzali, Giulia Buttiglione, Lucia Babini, and Ornella Pia D'Amato for their assistance with data collection.

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Table 1: Baseline demographics and clinical characteristics (N=58)

	All (*N*=58)	**WBT-lifestyle (*n*=30)**	**Lifestyle alone (*n*=28)**	***p*-value**
Mean age (SD), years	55.5 (6.6)	56.1 (6.8)	54.8 (6.5)	0.46
Sex, *n* (%)				0.096
Female	23 (40%)	15 (50%)	8 (29%)	
Male	35 (60%)	15 (50%)	20 (71%)	
Education, *n* (%)				0.59
High school or greater	29 (50%)	14 (47%)	15 (54%)	
Lower than high school	29 (50%)	16 (53%)	13 (46%)	
Marital status, *n* (%)				0.89
In a relationship	46 (79%)	24 (80%)	22 (79%)	
Single	12 (21%)	6 (20%)	6 (21%)	
Employment status, *n* (%)				0.22
Employed	39 (67%)	18 (60%)	21 (75%)	
Unemployed	19 (33%)	12 (40%)	7 (25%)	
Accommodation status, *n* (%)				0.58
Living alone	5 (8.6%)	2 (7%)	3 (11%)	
Living with others	53 (91.4%)	28 (93%)	25 (89%)	

Median diagnosis of diabetes (IQR), years	6 (3,12)	6 (2,12)	7 (3,13)	0.71
Median medical comorbidities (IQR), number	4 (2,5)	4 (2,6)	4 (3-5)	0.53
Taking insulin	13 (22%)	7 (23%)	6 (21%)	0.86

Figure 1: CONSORT study flow chart

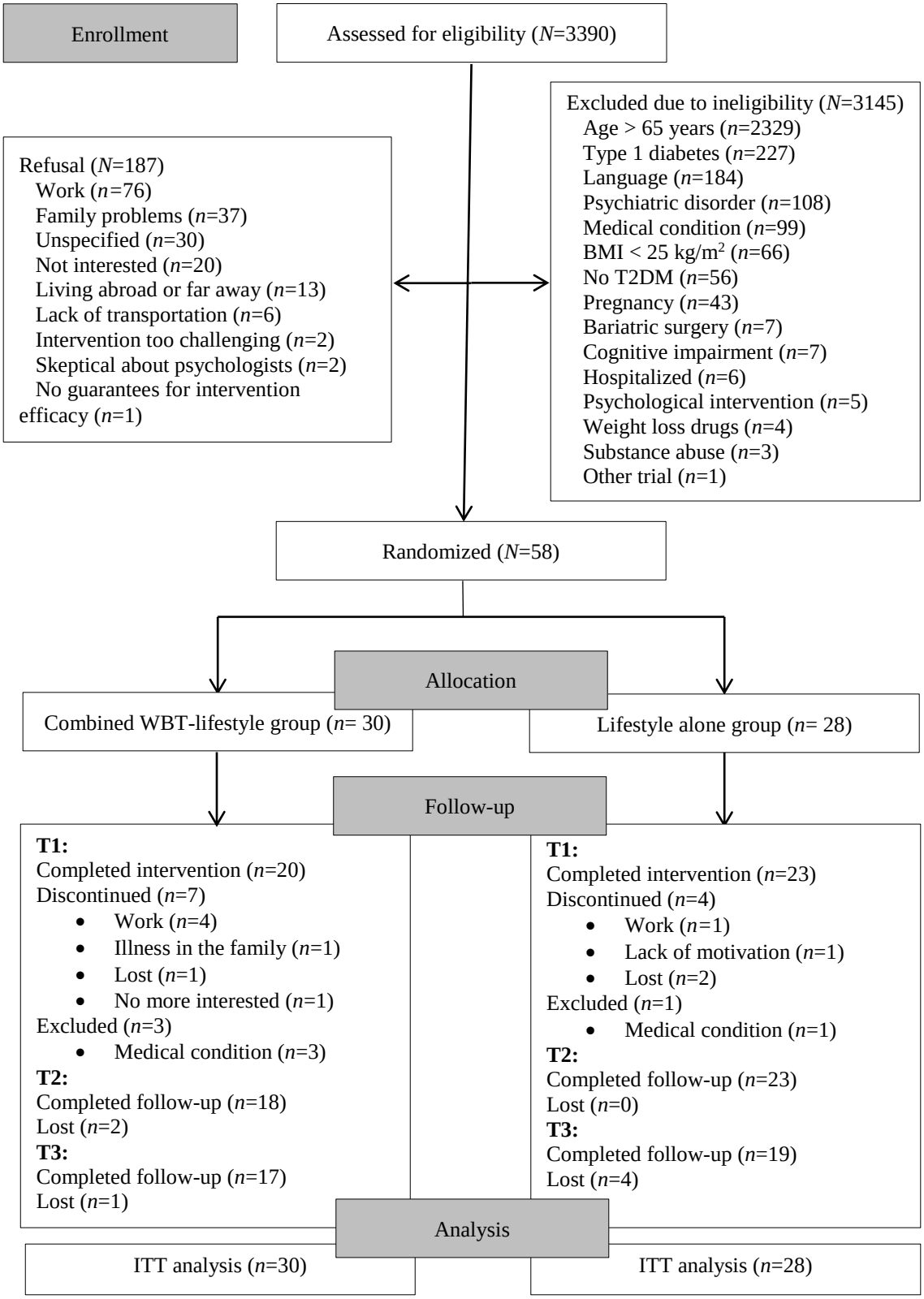

Figure 2: Marginal predicted means for select efficacy outcomes (*N*=58). ***Note:*** *Marginal predicted means reflect values adjusted for age, gender, site, and education from linear mixed model with baseline means constrained to be equal.*