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A 6-month randomised controlled trial to compare the effectiveness of telenutrition *v.* telenutrition supported by telemonitoring and health coaching in a weight loss programme: a study protocol

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Protocol Paper

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CRF, Case Report Form; RDN, registered dietitian nutritionist

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Abstract

One of the main challenges in weight loss programmes is compliance with diet and achievement of sustainable changes in eating habits and lifestyles. Most clients desire to lose weight quickly, rather than looking at *long-term* changes. The literature suggests applying telenutrition, owing to its convenience and easy access in combination with both telemonitoring and health coaching, where confounding factors in the diet are tackled. A 6-month randomised controlled trial will be conducted to compare the effectiveness of telenutrition *v.* telenutrition supported by weekly telemonitoring and monthly health coaching in a weight loss programme. Participants are obese and overweight adults of both sex groups, aged 20–50 years who will be randomised to join a control or an intervention group. A total of three visits will be scheduled for all participants: at baseline, after three months and after six months. This study aims to answer the question of whether participants following a weight loss programme supported by telemonitoring and health coaching will increase their weight loss and compliance to the diet in comparison with the control group. This will be the first trial to assess the impact of integrating telemonitoring and health coaching in weight loss programmes, including the evaluation of associated confounding factors such as general nutrition education, eating behaviour, sensory modalities and hunger, and stress. This trial will support dietary weight loss programmes, contribute to the emerging field of telenutrition and provide advice for clinical dietitians and health coaches to work together to help individuals lose and maintain weight.

Obesity is considered a chronic disease that causes a global burden and has been increasing since 2017, with more than 4 million people dying yearly from obesity-related diseases. Statistics showed that obesity is increasing in adults of both sexes and in children[(1)]. Other health concerns and complications resulting from obesity, such as diabetes, cancer, CVD and metabolic syndromes, can be prevented using several dietary strategies[(2)]. Weight loss programmes have been reviewed in the literature over the past few years, showing the importance of applying main components such as diet, physical activity, behaviour strategies, support groups and treatment strategies[(3)]. Such components are difficult to monitor owing to client preferences, cost and convenience, which may challenge clients to achieve their goals[(4)].

Evidence has demonstrated a change in dietitians' professional practice, where traditional consultation has shifted to being remote (online) consultations[(5–7)]. Telemedicine, as reported by the WHO and the American Telemedicine Association, is characterised by the remote provision of medical services and/or feedback from a patient to a clinician, or vice versa, via electronic communication technologies. Telemedicine may provide promising outcomes for patients than traditional care and reduces geographic barriers related to health management[(8)]. According to a review published in 2021, telemedicine interventions have shown successful results in terms of supporting patients to lose weight in populations with difficulty accessing healthcare professionals[(9)]. However, few studies have focused on telenutrition utilised by dietetics. In 2019, 'Telenutrition' has been defined by The Academy of Nutrition and Dietetics as 'the interactive use by a registered dietitian nutritionists (RDN) of electronic information and telecommunications technologies to implement the Nutrition Care Process (NCP) with

individuals at another location and following state laws'[10]. Telenutrition supports dietitians' consultations and provides access to healthcare for many clients at their convenience[7]. Intervention trials have confirmed that telenutrition interventions support access to dietary consultations and nutrition education specifically designed for obesity treatment[11,12]. The TEChnology for OBesity (TECNOB) study was one of the main randomised controlled trials that showed promising results over a 12-month duration via telenutrition consultation among patients with obesity and type 2 diabetes showing promising results up to 6 months[13]. In comparison with traditional counselling approaches, telenutrition was shown to have a stronger impact in increasing the score on participants' eating practices measures, which was seen as an improvement in several eating practices such as intake of fruits, nuts, sweets and soft drinks'[14]. In addition, a randomised controlled trial of a telenutrition weight loss intervention reported that retention, adherence and satisfaction rates were significantly higher in the telenutrition group than in the traditional consultation group[15]. Telenutrition has shown promising results with weight loss programmes when compared with traditional consultation, where 23·5 % of participants successfully completed the traditional consultation weight loss programme and 76·5 % successfully completed the telenutrition programme[16].

Nevertheless, dietitians face several challenges to implement a full NCP due to lack of anthropometric measurements and biochemical tests, where using 'telehealth devices' is crucial. In 2013, several smart health monitoring systems were assessed and compared based on their models and designs. Such devices may facilitate remote, real-time gathering and analysis of biomedical informatics data for managing chronic illnesses. Wearable health monitoring systems, small devices and biosensors that can measure different health parameters including heart rate, blood pressure, body weight and blood sugar levels[17]. Thus, telemonitoring can be added to telenutrition as a useful approach to monitoring chronic diseases such as diabetes and obesity and tackling the limitations of telenutrition. The telemonitoring of physical activity and nutrition has been shown to significantly improve weight loss and reduce the risk of metabolic syndrome[18]. Other studies have shown improvements in patients' motivation and lifestyle[19]. In addition, studies have shown that combining health coaching with telemonitoring positively affects clinical outcomes[20]. A cross-sectional study investigated three different telenutrition approaches, and the results have proven significant weight loss with clients in both the interaction and monitoring groups, where support groups with other clients made a significant reduction in weight compared with the group that was monitored[21]. One study examined the effect of telemonitoring with and without health coaching, in which both approaches supported long-term weight loss, and the data confirmed that the combination of both interventions tended to have a higher impact on weight loss[22]. Health coaching is recognised by healthcare practitioners, where health behaviour changes are believed to be improved via health coaching, and applying such strategies in weight loss programmes is essential for a healthier life[23].

Clearly, the shift in dietetic practices towards using telenutrition is spreading nowadays, with several approaches being utilised in weight loss programmes. Thus, very few clinical trials have been carried on telenutrition, which is worth investigating.

This study provides a detailed description of a two-arm randomised controlled trial among overweight and obese adults who will participate in a Novel Telenutrition Weight Loss Program, which is a new approach in using telenutrition by adding both telemonitoring and health coaching for significant weight loss results in comparison with a control group that will only use telenutrition.

Materials & methods

Research aims and objectives

The primary outcome of this study is to compare the effect home telenutrition supported by weekly telemonitoring and monthly personalised health coaching on weight loss *v.* home telenutrition only. The secondary aims are to determine significant differences in several predictive variables between the intervention and control groups, such as general nutrition knowledge, adult eating behaviour, sensory modalities and hunger, and stress level. In addition, the circle of life assessment will only be carried for the intervention group, which is associated with the telemonitoring and health coaching. This is defined as an assessment of participants' satisfaction with the circle of life aspects (spirituality, creativity, finances, career, education, health, physical activity, home cooking, home environment, relationships, social life and joy). Upon completion of the trial, reasons for dropping out of both groups will be identified.

Ethical approval

This study was conducted in accordance with the guidelines of the Declaration of Helsinki, and all procedures involving human subjects/patients were approved by the Research Ethics Committee (REC) at the Unit of Biomedical Ethics, Faculty of Medicine at King Abdul-Aziz University (approval number HA-02-j-008). Written informed consent was obtained from all the participants.

Study design

This study is designed as a two-arm randomised controlled trial in which participants are randomly divided into two groups (Fig. 1 Study Design Diagram):

1. Intervention group: This group will join a Telenutrition Weight Loss Program, which will be delivered via telenutrition supported by telemonitoring and health coaching. Registered clinical dietitian (RDN) will implement a full NCP (nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation). Each participant will complete 10–14 virtual nutrition consultations or until weight loss goals are achieved. In addition, each participant will be monitored weekly to record their weight, blood pressure, steps and circle of life assessment by a certified integrative nutrition health, aligned with monthly health coaching sessions, which is a total of six health coaching sessions.
2. Control group: This group will only join a Telenutrition Weight Loss Program via telenutrition only. Registered clinical dietitian (RDN) will implement a full NCP (nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation). Each participant will complete 10–14 virtual nutrition consultations or until weight loss goals are achieved.
3. All participants from both groups will be invited to attend three assessment visits: at the baseline visit, after three

Figure 1. A Consolidated Standards of Reporting Trials (CONSORT) flow chart.

months visit and after six months visit to carry out all required measurements for the study; anthropometric measurements, blood biochemical measures, 4-h diet recall, General Nutrition Knowledge (GNKQ-R), Adult Eating Behavior (AEBQ), Council of Nutrition Appetite Questionnaire (CNAQ) and Depression, Anxiety and Stress Scale (DASS-21). Medical follow-up by a family medical doctor will be provided by the end of each visit.

Power analysis

The sample size estimation was adapted from a previous study on the effectiveness of telemedical coaching on weight loss compared with a control group[22]. The sample size was calculated using a power of 80 %, significance level of 5 % and a dropout rate of 25 %. At least thirty-five participants are required per group to have a significant difference between the intervention and the control group, which corresponds to 3·7 kg (2·5 SD) in body weight in comparison with the control group, where only weights 1·6 kg (2·5) and 2·4 kg (2·5) were reduced[22].

Participants recruitment

Recruitment will be carried out through online platforms such as social media advertisements via Facebook and Twitter, which targeted the following demographic: individuals of both sex groups, aged 20–50 years and living in Jeddah City, Saudi Arabia. An advertisement flyer will be uploaded to all social media channels which have all relevant information about the trial to recruit participants who meet the study criteria. All participants will be screened for eligibility.

Inclusion and exclusion criteria

The study participants are adults of both sexes, aged 20–50 years who meet the following criteria: (1) obese or overweight based on the WHO BMI criteria and (2) informed and signed the consent form. Participants will be excluded for the following reasons: (1) if they are not capable of understanding or are not familiar with using the online applications required for the study, (2) pregnant and lactating women, (3) has a history of chronic diseases such as diabetes, CVD, thyroid dysfunction or any other endocrine abnormalities, (4) currently joining any type of weight loss programme or using medication to lose weight in the past three months and (5) not available for the whole 6 months duration of the trial.

Screening procedure

The inclusion and exclusion criteria will be checked during a screening visit using a Case Report Form (CRF). This form will include demographic information, anthropometric measurements, vital signs, medical history, medications taken, family medical history and physical examination performed by medical staff. At the end of the CRF, there is a checklist of inclusion and exclusion criteria. If the participant is eligible, they will be informed by an acceptance letter sent by email inviting them to the screening visit at the Food, Nutrition, and Lifestyle Unit in King Fahd Center for Medical Research. All participants will be randomly assigned by the principal investigator to the intervention or control group using a randomisation website (http://www.randomization.com). Each participant will have a specific code that will be provided to the researcher on the baseline visit; accordingly, participants will be informed about which group they will be joining. A Consolidated Standards of Reporting Trials (CONSORT) flow chart outlining the study schedule is shown in Fig. 2

Intervention group

Participants joining the intervention group will receive the following:

1. Telenutrition: Participants will complete virtual nutrition consultation sessions with a registered clinical dietitian (RDN). The RDN will complete a nutrition assessment including a dietary assessment through multiple 24-h dietary recalls[24]. The RDN will further discuss with the participants eating habits and challenges or difficulties towards eating as well as food preferences, dislikes and allergies and intolerances. Anthropometric and biochemical data will be reviewed and confirmed with the patient as well as clinical findings, medical history, and daily activity level and exercise routine. Subsequently, the RDN will determine the nutrition prescription and plan a calorie-reduced diet with a 500-calorie deficit based on the total energy expenditure which will be calculated using the Harris–Benedict equation and appropriate activity factor[25]. The RDN will set SMART (Smart, Measurable, Assignable, Relevant, Time-specific)

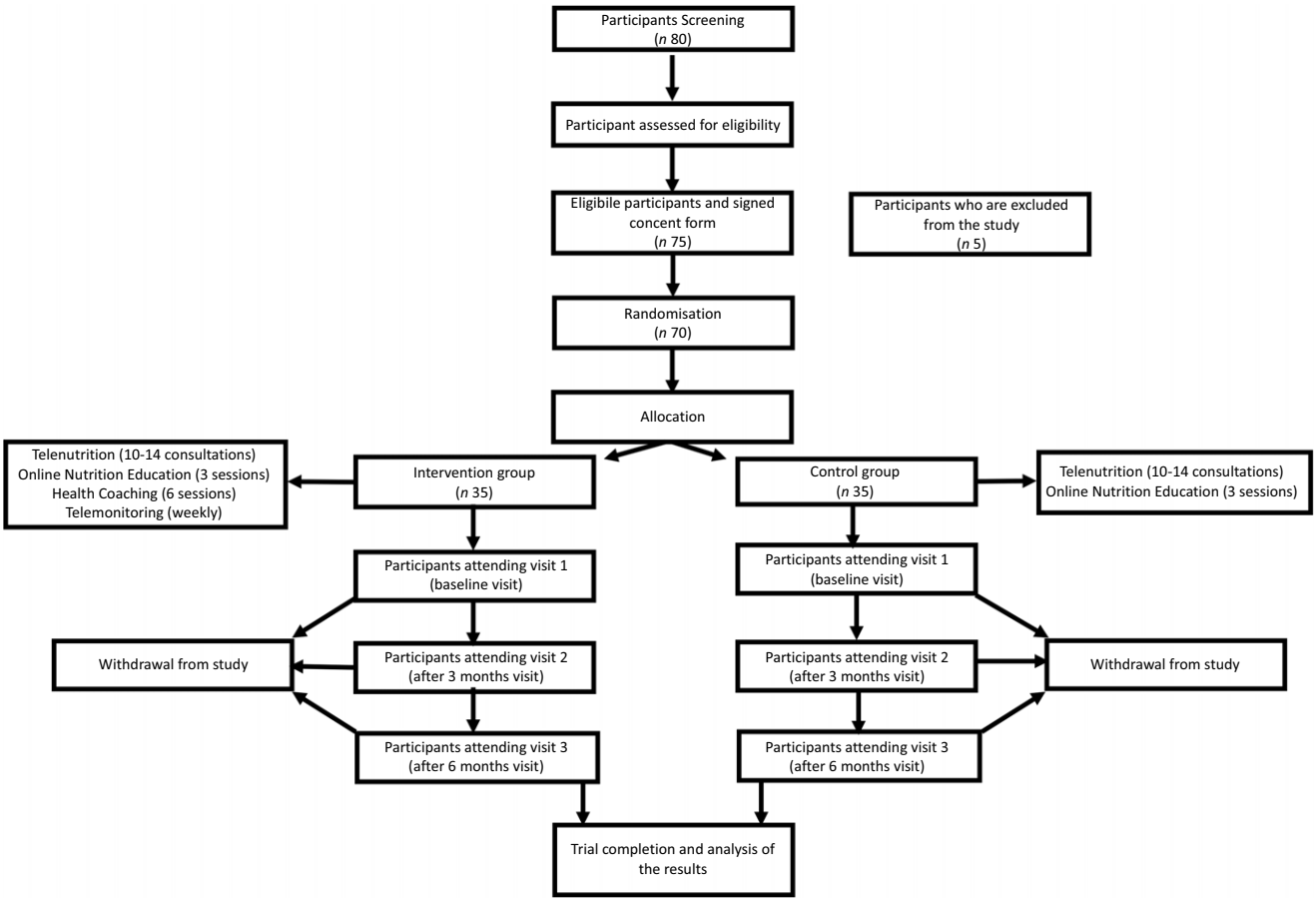

Figure 2. Study design diagram.

goals with the participant and discuss steps that can be implemented to achieve each goal[26]. The RDN will share with each participant a diet guide showing portion sizes, meal plans and recipes. For initial weight loss goal of 5–10 % of baseline weight within six months, participants need between 10 and 14 follow-up consultation or until weight loss goals are achieved[27].

2. Online Nutrition Education: Participants will receive three online educational workshops during the six-month period, starting with an online introductory session explaining the entire Telenutrition Weight Loss Program. Sessions will be delivered by both clinical dietitians and integrative nutrition health coaches. After the completion of each visit (after baseline visit, after three months visit and after six months visit), participants will receive a Zoom link to attend the sessions, which will cover the following topics: diet and health, tips in grocery shopping and integrative nutrition. Each session is 45-min long and starts with a 15-min reflection on the participants' compliance to the diet to ensure that participants are satisfied and retained in the programme.
3. Telemonitoring: Participants in the intervention group will be asked to self-record their body weight using self-measurement devices, including a weighing scale (Beurer GmbH, PS240), an upper arm blood pressure monitor (Geratherm Medical AG) and a pedometer (Spacare SpapedW24). Each participant will be invited on the baseline visit day to a one-on-one training session using each of the measuring devices provided, including printed brochures, to take home to confirm that all participants have all the resources needed for their self-measurements. An assessment of each participant's satisfaction with the circle of life aspects will also be conducted weekly. The research team in charge of training the participants will ensure that each participant had downloaded WhatsApp (https://web.whatsapp.com) and ensure the availability of Internet access in their homes, which is the main platform used for weekly communication. Thus, all telemonitoring results will be sent directly to the certified integrative nutrition health coach to provide feedback and personalised health coaching sessions.
4. Health coaching: Participants in the intervention group will be scheduled to attend monthly health coaching sessions with a certified integrative nutrition health coach. Health coaching sessions will be 45 min in duration, delivered in two types of settings: individually and in a group. The health coaching approach followed is an approach taught in the Institute for Integrative Nutrition[28], which focus on main aspects of life defined as 'the circle of life', which include spirituality, creativity, finances, career, education, health, physical activity, home cooking, home environment, relationships, social life and joy. Health coaching will start with a health history session to understand each participant's eating and lifestyle habits such as sleep patterns, cravings, smoking, as well as the context of any underlying health concerns or hereditary conditions. Through the monthly sessions, the health coach observes the telemonitoring readings and

supports the participant in setting monthly goals that are realistic, reachable and fit their lifestyle demands to be able to follow the diet plan and lose weight. In addition to goal setting, the health coach actively listens to the ongoing challenges that participants may face in their journey and works to increase their awareness by sharing relevant articles and resources. The main aspect of a health coaching programme is building a sense of commitment and accountability to achieve sustainable results that last beyond the programme. In addition, health coaches who join the study will have personal training expertise to focus on the physical activity aspect that is expected to be a challenge for the target audience chosen in the study. At least 20 min of exercise three times a week will be provided to the participants via demonstrations by coaches, recorded training sessions and/or referrals to join different types of exercises (aerobic, yoga, pilates or strength exercises). The physical activity plan will be designed based on participant accessibility and convenience, in addition to participant weight and capabilities.

5. Medical follow-up: Each participant will be assigned to a family medical doctor who will meet the participants in each of the trial visits (at baseline visit, after 3 months and after six months). According to the results of the biochemical analysis collected at each visit, medical reports will be sent to each of the participants to help with any alerts regarding undernutrition or any risks of undernutrition or high blood pressure. The results will also be provided to dietitians working on this study for consideration when planning their diets.

Control group

Participants joining the control group will receive the following:

1. Telenutrition: Participants will be complete virtual nutrition consultation sessions with a registered clinical dietitian (RDN). The RDN will complete a nutrition assessment including a dietary assessment through multiple 24-h dietary recalls[24]. The RDN will further discuss with the participants eating habits and challenges or difficulties towards eating as well as food preferences, dislikes and allergies and intolerances. Anthropometric and biochemical data will be reviewed and confirmed with the patient as well as clinical findings, medical history, and daily activity level and exercise routine. Subsequently, the RDN will determine the nutrition prescription and plan a calorie-reduced diet with a 500-calorie deficit based on the total energy expenditure which will be calculated using the Harris–Benedict equation and appropriate activity factor[25]. The RDN will set SMART (Smart, Measurable, Assignable, Relevant, Time-specific) goals with the participant and discuss steps that can be implemented to achieve each goal[26]. The RDN will share with each participant a diet guide showing portion sizes, meal plans and recipes. For initial weight loss goal of 5–10 % of baseline weight within six months, participants need between 10 and 14 follow-up consultation or until weight loss goals are achieved[27].
2. Online Nutrition Education: Participants will receive three online educational workshops during the six-month period, starting with an online introductory session explaining the entire Telenutrition Weight Loss Program. Sessions will be delivered by both clinical dietitians and integrative nutrition health coaches. After the completion of each visit (after baseline visit, after three months visit and after six months visit), participants will receive a Zoom link to attend the sessions, which will cover the following topics: diet and health, tips in grocery shopping and integrative nutrition. Each session is 45-min long and starts with a 15-min reflection on the participants' compliance to the diet to ensure that participants are satisfied and retained in the programme.
3. Medical follow-up: Each participant will be assigned to a family medical doctor who will meet the participants in each of the trial visits (baseline visit, after three months and after six months). According to the results of the biochemical analysis collected at each visit, medical reports will be sent to each of the participants to help with any alerts regarding undernutrition or any risks of undernutrition or high blood pressure. The results will also be provided to dietitians working on this study for consideration when planning their diets.

Data collection methods and instruments

Participants' health history, demographic information and visit measurements will be collected using the CRF. At each visit, secondary measurements will be collected, such as the 24-h diet recall, general nutrition knowledge, adult eating behaviour, appetite and stress.

Case Report Form

The CRF includes the following participant information: (1) screening visit information (demographic information, anthropometrics, vital signs, previous medical history, medications taken, family medical history and physical examination); (2) end of screening visit checklist (inclusion, exclusion and informed consent criteria) and (3) baseline information (anthropometrics, vital signs, demographic questions, medications and health history).

Anthropometric measurements

Anthropometric measurements, including systolic and diastolic blood pressure, weight, waist circumference, BMI and body fat percentage (body composition analyser), will be recorded during each visit using standardised equipment and techniques.

Blood biochemical measures

Samples were collected from the Food, Nutrition, and Lifestyle unit and sent to ROYA First Vision Laboratories at King Fahd Center for Medical Research to undergo several tests, including CBC, alanine aminotransferase, aspartate aminotransferase, albumin serum, alkaline phosphatase,γ-glutamyl transferases, direct bilirubin, total bilirubin, HbA1C, vitamin D, total cholesterol, LDL, HDL, TAG, thyroid-stimulating hormones, ferritin, C-reactive protein and total protein. The results are determined to be appropriate according to the quality control values provided within a specific range by the manufacturers (https://royakau.com/en/).

24-h diet recall

Participants' dietary intake will be recorded online in the 24-h diet recall during the three visits. Clinical dietitians will be assigned to use food models and portion size manuals to support participants in recalling their dietary intake (type, amount and cooking techniques) in the past 24 h. Both participants and investigators

will be required to have online consultations with the video on to ensure correct measurements and recall. Accordingly, the daily energy and nutrient intakes for individuals will be calculated using Nutritics (https://www.nutritics.com/en/).

General Nutrition Knowledge

General Nutrition Knowledge was assessed using the Arabic version of the revised General Nutrition Knowledge Questionnaire, which is an eighty-eight-item questionnaire consisting of four sections: (1) dietary recommendations consisting of eighteen questions, (2) food groups and nutrient sources consisting of thirty-six questions, (3) healthy food choices consisting of thirteen questions and (4) associations between diet, disease and weight consisting of twenty-one questions. The questions are in a multiple-choice format, and answers are scored by assigning 1 point per question. The first section includes recommendations and portion sizes for the main food groups. In the second section, the questions covered specific types of food and their salt, fat, protein and sugar contents. In the third section, the questions covered the best and healthier food choices. The fourth and last section covered the quality of foods and their association with increasing or decreasing risk of diseases, including knowledge related to weight management, such as reading food labels. All sections had questions with only one correct answer, which is recorded as 1 point. Demographic data and anthropometric measurements are recorded at each visit[29].

Adult Eating Behaviour

The validated Arabic version of the AEBQ, which is a five-point Likert-scale questionnaire consisting of thirty-five items that are part of eight subscales, will be used. The subscales include four food approach subscales to assess hunger (H), consisting of five items: food responsiveness (FR) consisting of four items, emotional overeating (EOE) consisting of five items and enjoyment of food (EF) consisting of three items. In addition, four food avoidance subscales will be used to assess satiety responsiveness (SR) consisting of four items, emotional under-eating (EUE) consisting of five items, food fussiness (FF) consisting of five items and slowness in eating (SE) consisting of four items[30].

Council of Nutrition Appetite Questionnaire

All participants were requested to complete a validated Arabic version of the CNAQ, which is used to determine taste, scent and hunger levels. An instrument that measures appetite will be scored on a five-point (A to E) Likert-type scale with verbally labelled categories. The total CNAQ score is the total score of the eight items, and a low score indicates a reduced appetite level; scores range from 8 (worst) to 40 (best). The questionnaire was composed of eight questions and took approximately 5 min to complete. Participants who completed the telenutrition weight loss intervention were contacted by the investigators and invited to participate the current study. Subjects who agreed to participate signed a consent form and completed the CNAQ[31].

Depression, Anxiety, and Stress Scale

The Arabic version of the DASS-21 (Lovibond & Lovibond, 1995; Moussa *et al.*, 2017) was used to measure the severity of symptoms common to depression, anxiety and stress. Individuals were asked to rate the presence of each symptom in the previous week. The DASS-21 comprises three subscales: depression, anxiety and stress. Each subscale consisted of seven items, and each item is rated on a Likert-type scale ranging from 0 'did not apply to me at all' to 3 'applied to me all the time'. The scores for each subscale range from 0 to 21. The higher the scores, the more negative the experience of depression, anxiety and stress during the previous week[32].

Circle of life assessment

Telemonitoring will be carried out via smartphones, and all targeted health parameters will be monitored weekly. Each participant in the intervention group will reflect on their satisfaction with and fulfilment with different aspects of life using a developed questionnaire (https://info.integrativenutrition.com/circle-of-life)[33]. A colour-coding system will be developed based on three colours: green, completely satisfied; yellow, not completely satisfied; and red, not satisfied[19].

Identifying reasons for dropout

The reasons for dropping out will be investigated using a semi-structured interview-based questionnaire. The participants' experiences of participating in online dietary counselling is the main topic of the interview questions. Participants will be inquired about their experiences by asking questions such as 'Please describe the personal reasons for dropping out'. The semi-structured interviews consisted of eleven questions and takes approximately 10 min to complete. Semi-structured interviews were adapted from a previous study[34]. Participants will be questioned on their experiences such as 'please describe your diet schedule', 'please talk about a successful diet schedule' and 'tell me about why you dropped out of your weight loss diet'. Interviews were recorded and typed electronically using Microsoft Word. Accordingly, answers will be defined and coded based on thematic content analysis as described below:

Theme 1: Personal reasons for dropping out of the diet, such as misunderstanding of diet, lack of motivation, conditions of stress and hormonal disorders, feeling harm to health, lack of mental and psychological preparation, and personal taste.

Theme 2: Family and social reasons for dropping out of the diet, such as social and family problems.

Theme 3: Diet characteristics as reasons for dropping out of diet, such as ineffectiveness of diet, expensive diet and dietary supplements, unavailability of food, unscientific and unconventional diets, and feeling wrong about the diet or non-palatable food.

Data analysis methods

The main outcome (weight loss) and secondary outcomes (dietary, biochemical, knowledge, behaviour and appetite changes) between the control and intervention groups will be analysed using the SPSS program version 26.0. Continuous data will be reported as mean and SD. Categorical variables will be reported as frequencies and percentages (%). A complete analysis will be performed at any time point. Between-group differences in continuous outcomes will be examined at all time points using an independent t test or the Mann–Whitney U test, depending on data normality. Changes over time will be examined using mixed models and a paired t test or Wilcoxon test, depending on data normality. The χ^2 test will be used for categorical variables. Statistical significance was set at $P < 0{\cdot}05$ (two-sided).

Data management

All data will be collected and stored by the principal investigator for 5 years and can only be accessed by members of the research group included in the manuscript. All documents are saved electronically and treated as confidential. If requested, participants could access their own data after completion of the trial by contacting the principal investigator.

Data monitoring and quality assurance

All data stored for the study will be monitored by the data management officer via specific electronic devices used for the study only which will be accessed by the principal investigator. All documentation used for the participants' visits will be revised, and final templates will be provided to the research assistants on booked clinic days.

Confidentiality

All study-related information will be securely stored at the study site. All participant information will be stored in locked file cabinets in areas with limited access.

Ancillary and post-trial care

All participants (eligible and ineligible) will be provided with a medical report consisting of laboratory results, vital signs and recommendations for any required supplementation by the family doctor working in the study.

Trial results and dissemination policy

All findings of the study will be published in an ISI journal, and the outcomes of the study will be shared with all participants.

Discussion

Telenutrition's main benefit is to support individuals to have access to services that are difficult to reach, and it is a great tool for those requiring weight loss; however, further research is needed to ensure that the population can adhere to the diet and lifestyle for a long period[9]. According to the TECNOB study[13] and several telenutrition-based studies, significant changes in body weight were observed in overweight individuals[11,15,16,18,35]. One of the main strengths of telenutrition is its impact on increasing participants' retention rates and reported adherence and satisfaction rates when receiving weekly follow-ups from registered dietitians via telephone and videoconferencing[15]. In another study, telenutrition had a higher impact on reducing dropout risk than traditional consultations[16]. However, research is still needed to find the ideal telenutrition model. As mentioned earlier, weekly follow-ups are powerful, and telemonitoring is needed. According to a previous study on weight loss, telemonitoring has a strong impact on both weight loss and improvement of metabolic biomarkers[18]. However, studies comparing different telenutrition strategies have confirmed that the highest mean weight loss was observed among participants who had more interactions with dietitians than among those who did not[21]. Thus, enhancing interaction with coaching and support is important[36,37], which was also confirmed in previous studies that adding telenutrition health coaching supports weight loss[38] and has also been seen to exhibit a long-term effect in comparison with telenutrition without health coaching[22]. This study aims to assess the impact of a newly developed telenutrition approach, which is supported by telemonitoring, and personalised health coaching carried out by a team consisting of a family medical doctor, a clinical dietitian and an integrative nutrition health coach. Currently, struggles have been observed due to daily stress[39], lack of awareness[40], incorrect motives[41] and poor quality of life[42,43], which may have caused significant challenges in committing to a diet plan and losing weight. This suggests the involvement of telemonitoring and personalised health coaching, which has been introduced to improve lifestyle for a longer period following specific key variables[44] or so-called 'the circle of life'. The current research aims to answer the question of whether the new model of telenutrition combined with telemonitoring and personalised health coaching can tackle specific aspects of life that may have influenced client satisfaction and their commitment to changing their eating habits and lifestyle over a long period of time.

However, using technology may be challenging for specific age groups and communities where a smartphone is required. One study described that the main issue that older populations may face is the ability to use specific applications, where one-on-one coaching and training is needed[45]. In addition to the various availabilities of telehealth platforms, they have different impacts on weight loss programmes. Previous studies evaluated existing patient telemonitoring platforms to help health professionals select the best telemonitoring platform for their clients. However, these studies did not reflect all regions and more studies are required in the Middle East and Asia[46]. In addition, existing telemonitoring platforms require biomedical instrumentation and user interfaces which has been seen to have several issues and challenges, especially for the age group and community targeted in the study, where language and advanced technology may be significant barriers to communication[47]. Thus, the current study will be testing the effectiveness of a developed model using simple and direct applications such as texting using the WhatsApp and health coaching using Zoom videoconferencing. Such approach has been chosen for its convenience and familiarity with the targeted audience.

One of the main limitations that the current study may face is the remote application of the nutritional assessment[48], which requires videoconferences, training and self-recording. A previous study investigated the reliability of self-reported weight for the management of heart failure, where several errors have been identified due to rounding or patient preferences for numbers ending with 0 or 5[49]. Therefore, the current study will provide training and printed brochures to overcome the potential errors associated with self-recording. In addition, each participant is required to physically attend the clinic for a full nutritional assessment, which supports data auditing and accuracy. Upon successful outcomes of the trial and publication of the study's initial results, the research team plans to map available platforms that are suitable for weight management programmes and available in both English and Arabic to be easily utilised by the targeted population.

Despite the limitations, the current study has several strengths, including considering quality of life and supporting participants in setting non-dietary goals such as sleep, social relationships, physical activity and spirituality, which are considered confounding factors for weight gain and have a strong impact on cravings[50] and emotional eating[51]. Another strength is that the current study is the first to implement an integrative nutrition approach to weight loss carried out by three health professionals (family medical doctor, registered clinical dietitian and an integrative nutrition health coach), showing interdisciplinary practice tackling the factors influencing participants' ability to follow a specific diet plan and lifestyle. This may have an impact on the greater weight loss, which may persist for a longer period than with telenutrition alone[22]. Furthermore, the outcomes of the current study may result in the design and development of an innovative platform that combines the practices of dietitians, health coaches and family medical doctors to support the population in reducing obesity and other metabolic syndromes using self-measurement devices that can be connected directly to the platform for accurate telemonitoring and effective health coaching.

Trial principal investigator

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Organisational structure and responsibilities

Principal investigator
Designing and managing the study
Preparation of protocol and revisions
Fund and budget administration
Leading the publication of study reports
Signing content forms

Co-investigators
Revising and agreement of final protocol
Advertisement and recruitment of participants
Preparation of investigators CRFs (Case Report Forms)
Preparation of materials and methods
Clinics booking

Family medicine doctor
Eligibility requirements and participants' medical files
Recommendation and acceptance reports

Clinical dietitians
Consultation, diet planning and nutrition assessment
Follow-up

Health coach
Health coaching sessions
Follow-up

Telemonitoring manager
Weekly monitoring

Data management
Sample size calculation and randomisation
Statistical analysis
Results presentation

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N. M. S. E.: principal investigator, main project supervisor, applicant in the human trial design and corresponding author; E. A. A. and K. M. Q.: applicant in the human trial design and guidance in recruitment, screening and health assessment; R. M.: applicant in the human trial design and guidance in nutrition counselling and diet planning; R. R. S.: applicant in the human trial design and guidance in weekly telemonitoring; S. M. S. E.: applicant in the human trial design and an integrative health coach who provided health coaching sessions for all participants; S. E.: applicant in the human trial design and provided statistical expertise in the clinical trial design and conducting the primary statistical analysis. All authors are grant owners and contributed to the trial. All authors contributed to drafting the manuscript and approved the final manuscript.

There is no conflict of interest to declare.

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