WaznApp, a self-directed mobile intervention to promote weight control among employees of a Lebanese university: Study protocol of a pilot randomized controlled trial

Study Acronym: WaznApp

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1. Introduction

1.1 Background and Rationale

Noncommunicable diseases (NCDs), also known as chronic diseases, are one of the major global public health challenges of the 21st century, being responsible for about 40 million deaths per year, 15 of which are premature (i.e. between 30 and 69 years) [3]. The majority of these deaths occur in low- and middle-income countries. According to the WHO's global report, cardiovascular diseases, cancer, diabetes, and chronic respiratory diseases are responsible for 82% of all NCD deaths [4]. In Lebanon, the prevalence of NCDs accounts for 85% of all deaths. NCDs are the product of four main risk factors: tobacco use, physical inactivity, the harmful use of alcohol, and unhealthy diets, which, in turn, lead to four key metabolic changes (raised blood pressure, overweight and obesity, raised blood glucose, and raised cholesterol) [3]. With regards to overweight and obesity, globally, in 2014, there were more than 1.9 billion overweight adults, representing the 39% of the world population. Of these, 600 million were obese [5]. In Lebanon, the prevalence of obesity and overweight is 65.4% (obesity accounting for 27.4% and overweight for 38%) [6]. The fundamental cause of obesity and overweight is an energy imbalance between caloric intake and caloric consumption, which is due to global trends of increased availability and intake of energy-dense foods that are high in fat, and insufficient physical activity, due to environmental factors, including the sedentary nature of many forms of work, modes of transportation, increased urbanization [5]. All these risk factors are preventable, as they can be addressed by modifications in the environment and in one individual's lifestyle and health behaviors (i.e., increasing physical activity, reducing sedentary time, following a healthy diet, etc.) [7].

The effectiveness of nonsurgical and behavioral weight management interventions has been demonstrated in several systematic reviews and meta-analyses [8,9]. For example, commercially available weight loss treatments, such as *WeightWatchers*, and pharmaceutical products, such as *Qsymia*, were the most cost-effective strategies to achieve weight loss [10]. Effective behavioral interventions should include both physical activity and dietary components to reach larger and sustained effects [11]. Self-monitoring is one of the most effective behavior change techniques [12] included in behavioral weight loss interventions, as evidence shows that people who report weight monitoring on a daily or weekly basis tend to be more successful in attaining weight loss goals [13,14]. Self-monitoring improves awareness of caloric and food intake, increases self-efficacy, and permits evaluating any change or progress over time [15]. However, long term weight loss and maintenance interventions that are delivered face-to-face usually require substantial work of a specialist workforce and sizeable resources, both from the participants and the service providers.

In the past decade, with the help of new technologies, new strategies for behavioral weight management interventions have been developed [16–20] to provide users with the support necessary to attain weight loss and, at the same time, contain the costs [21]. Self-directed interventions are those "that require minimal professional contact (for example, provision of initial instructions) or no professional contact and can be easily used with existing infrastructure and in the context of users' everyday lives" [22]. Mobile phones, and particularly mobile phone apps, have been considered a convenient intervention platform since they are portable, appealing, and universal [23]. The attention towards mobile Health (mhealth) apps is also justified by the high penetration rates of these technologies. In 2014, 1.7 billion smartphones were sold worldwide, with 6.5 billion mobile subscribers [24]. In Lebanon, the penetration rate of smartphones has expanded exponentially in the last few years and reached 70% in 2014, about twice the rate of 2012 (36%) [25].

Modern mobile phones, so called "smartphones" are the ideal platform to deliver Just-in-Time Adaptive Interventions (JITAIs). JITAIs promptly provide support through skill building (coping, making decisions, planning, etc.), emotional support (encouragement, etc.), and instrumental support (feedback, etc.) features [26,27]. In addition to the options of being administered in-person, though a computer, and through a smart watch, mobile devices are adequate for delivering feasible and scalable JITAIs given the smartphone technology advancements that are providing users with continuous monitoring

and personalized coping strategies [26]. Health behavior change in physical activity [28,29] and obesity/weight management has been increasingly supported by the development and use of JITAIs [30].

According to the WHO's global action plan for the prevention and control of NCDs [31], workplaces are one of the most important settings for health promotion as they are the gateway to a large number of people (about 65% of the world's population is employed) [32]. In the last decades, many public health efforts have been made and numerous interventions have been conducted to tackle these problems. There is a wide evidence supporting the effectiveness of workplace interventions for the prevention of obesity [33–36], and many national governments adopted policy decisions for promoting health through workplaces. In response to the WHO call for action, the Lebanese Ministry of Public Health has released in 2016 a plan for the prevention and control of noncommunicable diseases [6], which, however, does not include workplaces as a setting for priority interventions.

Previous related research

This study is part of a project entitled "Can commercial mobile apps for weight management be used in interventions? Bridging the gap between usability, theoretical adherence, and user experience", and is based on the results of a user-centered heuristic evaluation formative study, which was previously approved by the local IRB (ref. nr. FHS.MB.01). The aim of the heuristic evaluation study was to understand how members of the AUB employee community perceive six weight-management apps, recently reviewed by experts [37]. The six apps were *Lark, MyFitnessPal, SparkPeople, MyPlate, My Diet Diary,* and *My Diet Coach PRO* and were selected because they achieved the highest total scores on the Mobile App Rating Scale (MARS)[38], an expert-targeted instrument that has been recently developed to evaluate health app quality. In the heuristic evaluation study, 36 employees were randomly assigned to use and review one of these apps for two weeks. At the end of this period, they submitted their evaluation of each app quality, based on the user-version of the MARS scale (the so called "uMARS" scale) [39]. According to the user evaluation, three apps achieved the highest mean ratings for total app quality score (*Lark* = 4.0; *MyPlate* = 3.8; *MyFitnessPal* = 3.7), as well as subjective quality (*Lark* = 3.4; *MyPlate* = 3.3; *MyFitnessPal* = 2.7). However, some sub-domain scales showed suboptimal internal consistencies, suggesting high variability in the way users interpret the instrument. This issue was confirmed by inter-rater agreement estimates, which demonstrated how not every user rated the app the same way as others [40]. Future research should be aimed to validate the instrument and understand whether these apps can be considered valid instruments to promote behavior change and sustained weight control.

The challenges encountered in the previous study were mostly related to recruitment and data collection. Recruitment lasted 4.3 months in order to reach the expected sample size (six users per app), following recommendations from heuristic evaluation literature [41,42]. The method for recruiting participants was initially email invitations to complete an eligibility survey on LimeSurvey. The emails were randomly-selected from the Academic Core Processes and Services upon IRB request. After three weeks and two reminders, the response rate was 3%, suggesting that randomly selecting users might not be a viable solution to reach those who are interested in losing weight or engaging in research projects. To achieve the expected sample, we asked the approval to use social media channels. With the new recruitment strategy, we managed to get additional 145 responses to the eligibility survey, 29 of which resulted in enrolled participants.

1.2 Study Objectives

The overarching aim of this study is to assess the feasibility and preliminary efficacy of a self-directed weight control intervention, based on two mobile apps (Lark and MyFitnessPal), targeting employees of an academic institution. By weight control we mean weight loss, weight gain prevention, and healthy weight gain. Specifically, the study aims to:

1) Evaluate the acceptability and feasibility of using: commercially available mHealth apps as delivery modes for a self-directed behavioral intervention; instruments such as app quality (uMARS), dietary behavior (ASA24-2016), and physical activity (IPAQ-S).

2) Evaluate the feasibility of implementation strategies, retention, and adherence to the study, fidelity to the protocol, assessments, and data collection procedures.
3) Evaluate the effects of the interventions on weight-related outcomes (e.g., weight, BMI, waist circumference), as well as in cognitive and behavioral factors related to weight loss (motivation to lose weight, to engage in physical activity, and follow a healthy diet).

1.3 Design Overview

The study is a single-center, parallel randomized controlled trial with two study arms (intervention and control). The intervention arm will use *Lark*, a mobile coach, which provides a just-in-time adaptive intervention (JITAI)[43,44] by providing motivational feedback, goal setting, emotional social support, among other change techniques. *Lark* acts as an adaptive intervention (see for example the researcher-based CITY trial [45,46]). *Lark*, developed with the help of behavior change experts from the universities of Harvard and Stanford, is an app that provides interactive counseling through a chat-style interface. The content of the messages is based on the user interaction and is grounded on behavior change techniques, such as goal setting, reviewing behavioral goals, feedback, and social support [37]. The users input their activities, foods or weight, but the app tracks automatically their active time using proprietary algorithms, using features of the phone, including triaxial accelerometers. Lark has recently been employed in an observational study, involving 70 diabetic patients, who lost 2.4% of their weight at baseline after about 15 weeks [47].

The control group will use *MyFitnessPal*, a calorie counting app which does not include JITAI components, but allows users to keep track of their caloric intake and energy expenditure. *MyFitnessPal* (MFP) is a calorie counting app, which relies on user input for foods. Compared to other similar apps such as *MyPlate*, in MyFitnessPal, foods can be added from an extensive database by hand and by scanning their barcodes. Recipes also can be imported from the internet by URL [48]. Compared to another popular app (*Lose It!*), *MyFitnessPal* allows to automatically track activity through the phone or through integrations with many wearable devices [49]. Considered one of the most popular apps for dietary tracking [50], MyFitnessPal has been effectively used to promote dietary advice and reduce sodium intake in a recent RCT [55]. The app provides the users the possibility to set weight and caloric goals, reviewing them goals, and to receive feedback. However, this app acts as the control condition, as it provides limited social support, which is present in *Lark* and it is an important feature that is generally lacking in calorie-counting apps [51]. *MyFitnessPal* has been utilized in few weight-loss trials, showing some positive effects in weight reduction when employed as a supplement to telephone coaching [52], but small, no significant effects when used as a standalone tool [53,54].

2. Methods: Participants, Interventions, and Outcomes

2.1 Population and Setting

Participants are employees working full- or part-time at the American University of Beirut (AUB) and its Medical Center (AUBMC). Employees include any faculty, academic support staff, and research assistants. Even if this is a workplace intervention, targeting a vulnerable population, accordance to the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), the employer did not influence the design of the study, its methodology, nor recruitment procedures. The recruitment strategy does not rely on the endorsement of any AUB/AUBMC authorities. Participants will be informed orally and through the written consent that their participation is completely voluntary, free of charge and no penalty will be pressed for those not willing to participate.

2.2 Eligibility Criteria

2.2.1 Inclusion criteria

To be enrolled in the study, employees must fulfil the following criteria:

1. Be an employee of the American University of Beirut (AUB) or its Medical Center (AUBMC).
2. To be able to read, write, and understand English.
3. To own a smartphone with either Android (v4.4 or above) with or iOS (v8 or later).
4. To be interested in better controlling their weight (i.e., losing weight, preventing weight gain, maintaining weight lost, gaining weight in a healthy way).

2.2.2 Exclusion criteria

Individual who meet any of the following criteria cannot participate in the study:

1. Students, who cannot prove their status as full-time or part-time employees at AUB or AUBMC.
2. Employees who are not able to read, write, and understand English.
3. Employees who do not own a smartphone with either Android (v4.4 or above) or iOS (v8 or later).
4. Employees who have physical disabilities preventing them from exercising or walking.
5. Employees who are on a special diet for treatment of chronic conditions (e.g., Diabetes).
6. Employees who are diagnosed with anorexia or bulimia nervosa.
7. Employees who are under weight loss medications.
8. Employees who have undergone bariatric surgery in the past 3 months.

2.3 Interventions

2.3.1 Intervention Arm

Participants in the intervention arm will use for 12 weeks the pro version of a mHealth app called "*Lark*", developed by Lark Technologies Ltd. Lark is a coach app, which has been downloaded more than a million times from the two commercial app stores (Google Play for Android phones and iTunes for iOS phones) and has been rated the best app by Google in 2016, and one of the top 10 apps in iTunes in 2015. *Lark* uses several variables to generate smart and empathic conversations. Variables include activity, sleep, meals, weight, and height data, weight goal set by the user/Lark coach, activity goal set by user/Lark coach, starchy food goal set by user/Lark coach. Lark also keeps track of user input, for example what medications they are taking, how adherent they are to the medications, what their barriers are, when the user would like to be reminded to weigh themselves, and how many times they reach out to their medical provider through the app. Lark keeps also track of user entered feelings, accomplishments, and if they mentioned being sick, or if they follow a special diet (e.g. paleo, vegetarian, dairy free, etc.). Lark also keeps track of when the user started, which conversations they have seen, where they are in the program, and the time of day. Lark uses all these variables to create a dynamic coaching system, constantly changing and adapting to the user in the moment and over time. Each conversation is pre-programed and hand-crafted by Lark's team of nutrition, exercise, and behavior change experts. This degree of variation in the conversations keeps users engaged with the product, and the Lark coach in turn can offer information and emotional interventions at exactly the moment they are needed. This kind of smart feedback enhances user learning. Further, the Lark program and each individual conversation is designed to promote user motivation and resilience in the face of setbacks. For these features, *Lark* provides a just in time adaptive intervention [27].

According to a previous review of mHealth apps for weight management [37], Lark includes features that enhance change techniques underpinning behavior change. Following the Behavior Change Techniques taxonomy [56], Lark allows users to self-monitor their behavior, set and review behavioral and outcome goals (e.g., activity, weight), receive feedback on their progress, receive social support from the coaching app. Furthermore, the app is one of the few that provided information from credible sources [56], being developed in collaboration with researchers from Stanford and Harvard universities.

2.3.2 Control Arm

Participants in the control arm will be assigned to use *MyFitnessPal*, one of the most downloaded calorie-counting apps, which has a database of more than a million food items [57] and offers the greatest connectivity with activity tracking and wearable devices and services [49]. Similar to the intervention arm,

they will be instructed to use the app for 12 weeks. MyFitnessPal does not include JITAI components, but allows users to keep track of their caloric intake and energy expenditure. *MyFitnessPal* has been employed in an intervention targeting overweight primary care patients [53], showing limited evidence of effectiveness in clinical settings. According to the previously cited review of mHealth apps for weight management [37], *MyFitnessPal* has features that can be associated with effective behavior change techniques, including: self-monitoring of behavior and outcomes, goal setting and feedback (similar to Lark). In *MyFitnessPal*, social support is limited to comments and 'likes' from friends of its restricted user community, therefore tackling the techniques of "social comparisons" and "social reward" [56]. *MyFitnessPal* acts as an active control arm, as it relies almost exclusively on self-control, compared to *Lark*, as the latter provides an emotional social support from the coach, who provides positive enforcement and motivational messages to further encourage behavior change.

2.3.3 Additional Components

This study is based on and delivered almost entirely through mobile phones. Face-to-face interactions with the research team will be kept at minimum and used only to ensure that the mobile apps have been installed correctly, and there are no issues related to the use of technology during the intervention period. Participants will be instructed via manuals and tutorials delivered via email on how to download and use the apps, complete the surveys, and how to use the food composition tables for use in the Middle East [58], available from the local library. Manuals for completing dietary assessment using the online Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool, version 2016, are available directly on the tool's website. Emails will be used to communicate with study participants and to send them links for completing intermediate and follow-up assessments online.

2.3.4 Incentives for Participation

Participants will not receive any payment for their participation, but they will be awarded "*WaznApp karma points*" (WAKpts) for completing tasks related to the study. Karma points are a non-monetary measure of contribution to the study [59], and are awarded when participants duly fill the online questionnaires and food records. Each question filled in is worth 1 (one) WAKpt. The points are awarded as follows: the online baseline survey is worth **76** WAKpts; each of the three baseline ASA24 food records is worth **50** WAKpts (maximum 150 points); the intermediate surveys (weeks 4 and 8) are worth **41** and **21** points respectively; the final survey is worth **83** points; each of the three final ASA24 food records is worth **100** points (maximum 300 points). The maximum points are calculated as follows:

Baseline + Baseline ASA24 + Intermediate 1 + Intermediate 2 + Final + Final ASA24 =
76+150+41+21+83+300= 671 WAKpts

If the participants collect **at least 600** points, they will enter the final raffle, which will make available different Fitbit products (e.g., *FitBit Alta or Charge*, worth about $130 each). A Fitbit encourages and assist individuals in attaining their health and fitness goals by tracking several parameters such as their physical activity levels, weight, sleeping patterns, etc. (Fitbit, 2017). A draw for the Fitbits take place at the end of the study, by the end of June 2018.

In any draw chances for winning depends on the number of individuals entering the draw. Given the condition that anyone can enter the draw but that not everyone will complete all surveys, chances for winning one "Fitbit" are difficult to estimate. The research team will randomly select the winners by producing a computer-generated random sequence. The computer will collect all registered names and randomly select 5 winners. Winners will be notified by email, which will include the arrangements for distributing the prizes.

2.3.5 Administration of the Intervention

The intervention is delivered by the apps in an automated way. The research team nor the company producing the apps have direct contact with participants and will not prompt their participation. The

research team will send emails to participants only to remind them about data collection procedures. All research assistants have undertaken Collaborative Institutional Training Initiative (CITI) training and acquired certification. Nurses collecting data and eligibility information will be trained before the study start. The research team will meet with the nurses and provide instructions on how to fill the forms and to check the employees' eligibility status.

Intervention fidelity will be monitored weekly, through meetings with research assistants, which will be minuted. Participants' compliance with the intervention will be assessed through the email data collection points at baseline, Week 4, 8, and 12.

2.4 Outcomes

In this study, primary outcomes are those related to the feasibility, whereas secondary outcomes are those related to the preliminary efficacy. The timeline for data collection is specified for each outcome below. Considering the nature of this study, we will collect data mostly through mobile-friendly, online surveys.

2.4.1 Primary Outcomes

Feasibility measures. As done in other similar trial [60], feasibility measures include quantitative rates of recruitment, adherence and retention. Adherence to the study will be based on the number of data collection points completed and on qualitative feedback related to the study requirements. For *Lark* users (intervention group), we will use the logs of the app about quality (i.e., detail, accuracy) and quantity of meals logged, daily activities logged, weight, sleep duration, and the number of conversations with the Lark coach as measures of intervention adherence. Retention rate will be calculated at the end of the study based on the number of participants who successfully complete the study, excluding drop outs. For both intervention and control groups we will ask participants to provide information about their weekly app usage (hours/week). In Week 4, 8, and 12 surveys, we will add instructions on how to find the information on iPhones or Android phones, using the free app called "*Frequency: App Usage Tracking*".

Acceptability measures. Acceptability will be assessed using quantitative indices, such as the self-reported app quality. App quality will be assessed through the user version of the Mobile App Rating Scale – uMARS [39]. The uMARS scale, based on the original, expert-oriented MARS scale [38], provides a measure of app quality based on the average of four sub-domains: engagement, functionality, aesthetics, and information. Each of the sub-domains is based on the average value of multiple items, assessed through 5-point Likert scales (engagement: 5 items; functionality and information: 4 items; aesthetics: 3 items). The uMARS includes also 4 items that are aimed to address a subjective quality domain, which are: Would you recommend this app to people who might benefit from it? How many times do you think you would use this app in the next 12 months if it was relevant to you? Would you pay for this app? What is your overall star rating of the app? In the uMARS developmental study [39], the total scale and sub-scales achieved good and excellent internal consistency: engagement (Cronbach's alpha = 0.80); functionality (alpha = 0.70); aesthetics (alpha = 0.71); information (alpha = 0.78), total (0.90), and satisfaction (alpha = 0.78). In our previous heuristic evaluation study, internal consistency for each sub-domain of the uMARS scale showed some inconsistencies and sub-optimal results. Test-retest reliability of the uMARS scale will be assessed to establish whether the instrument can be used reliably across the sample over time. As the uMARS tool requires that users utilize the app before rating it, app quality requires measures will be collected at Week 4 and at Week 12.

Qualitative acceptability feedback related to the program will be collected at each data point through open-ended questions ("Do you have any concerns about the *study procedures*? Write a comment in the field below"; "Do you have any concerns about the *app you have used*? Write a comment in the field below"; "Do you have any concerns about the *questionnaires*? Write a comment in the field below"). Satisfaction with the program will be assessed through a 7-point rating scale (semantic differential) ranging from extremely satisfied to extremely dissatisfied. An open-ended question will give participants the option to elaborate on their response. These measures are calculated at the end of the study (Week 12).

2.4.2 Secondary Outcomes

Preliminary efficacy measures include weight-related outcomes (absolute weight and waist-circumference), behavioral outcomes (physical activity and diet), and cognitive factors (motivation to lose weight).

Weight-related outcomes: Absolute weight and waist circumference which will be measured with a standard scale at baseline and Week 12, by assessors blinded to arm allocation from AUBMC University Health Services. Intermediate self-reported measures of weight will be based on weekly check-ins, automatically prompted by the mobile apps, and collected through online forms at Weeks 4 and 8.

Physical activity: We will encourage participants to keep the phone with them in order to track steps and active time, as the phones automatically collect the number of steps walked using built-in accelerometers. Activity information integrates with *Google Health Kit* or *Apple Health*, and Samsung S Health. Participants will be asked to read and report average weekly measures of steps walked and/or daily/weekly active time at Week 4, Week 8, and Week 12. Lark automatically tracks the amount of active time per day, whereas *MyFitnessPal* can estimate the amount of steps walked using the phone accelerometer or external, third-party devices such as Fitbit, Misfit, Apple Watch, etc.

Since not everyone has their phone with them all the time to track activity, we will also use the International Physical Activity Questionnaire, short form (IPAQ-SF) [61], which is based on one of the most widely used questionnaires to assess physical activity [62]. The IPAQ-SF has shown acceptable reliability in specific populations, such as patients affected by schizophrenia [63], rheumatoid arthritis [64], or among older adults [65], and pregnant women [66]. It has also been used in large population studies [67] and in . Despite a recent systematic review showed that the IPAQ-SF is associated with low criterion validity (i.e., it tends to overestimate physical activity levels compared to objectively assessed measures) [68], another review has demonstrated that the instrument has excellent test-retest reliability [62]. Most importantly, the IPAQ-SF is also well received and more feasible to use, as it is perceived as less daunting than the long form showing similar reliability and validity estimates [69]. The IPAQ-SF requires respondents to estimate how much time they spent while doing activities in the previous week, in four domains: vigorous or moderate physical activity, walking and sitting. A total physical activity score is calculated by summing the time spent in each domain. Total physical activity score and sub-domain scores can be expressed in hours/week, or converted to metabolic-equivalents (METs), following the IPAQ scoring protocol [70]. MET values were derived from the IPAQ Reliability Study [69] and an average MET score will be derived for each type of activity using the compendium of Ainsworth et al. [71]: 1 MET equals the energy expenditure of sitting down quietly, 3.5 ml O^2/kg/min. Physical activity will be assessed through the IPAQ-SF questionnaire at baseline and Week 12.

Dietary intake: As this study is a self-directed intervention with minimal contact, to reduce researcher and participant burden, dietary intake data for (24-hour recalls/food records) will be collected and analyzed using the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool, version 2016, developed by the National Cancer Institute, Bethesda, MD. Compared to other dietary assessment tools, such as food frequency questionnaires (FFQ) and dietary records, 24-HR dietary recalls and food records require less cognitive effort to complete, are best suited for short-term dietary assessments in intervention studies, are less prone to overall bias, systematic error and reactivity (i.e., participants who are aware of their behaviors being measured, are more likely to change their dietary behavior) [72,73].

ASA24-2016 is based on the Automated Multiple Pass Method (AMPM), developed by the United States Department of Agriculture [74]. The multiple pass approach in 24-hour recall consists of 8 modules: a meal based quick list, meal gap review, detail pass, final review, forgotten foods, last chance, usual intake question and supplements module. It provides a detailed assessment of dietary intake over the past 24 hours including food, drinks and supplements, as well as timing, form, portion size, the way food has been prepared, consumption of additions such as sugar, cream, dressing, etc., in addition to the source/brand of food. The 2016 version of the system includes also pictures of portions which are deemed to reduce overestimation or underestimation of food intake [75]. Since its release date (April 2016), ASA24-2016 has

been used in 882 studies and 37,090 recalls have been completed. Various versions of ASA24 have also been used in weight loss self-directed interventions [76–78].

The automated version of ASA24 generally showed good reliability compared to interviewer-administered version [79] or to measures of true intake [80]. The ASA24-2011 version has been validated against and shown close agreement with interview-administered 24-hour dietary recalls among adults and children [80,81]. In this study, participants will complete an ASA24 at baseline and at the end of the intervention. The ASA24-2016 will be used on 3 non-consecutive days; on a week day and a weekend day. Before submitting the baseline assessment, participants will be instructed to use the tool during an initial orientation meeting. They will be given access to the online platform where they will submit their entries will be asked to recall food, drinks or supplements they consumed in the last 24 hours. The questionnaire can be accessed via mobile phones, using a responsive web-interface, available from the following link: https://asa24.nci.nih.gov. Energy and macronutrients estimates will be computed using the Nutritionist Pro software, using the USDA database (version 5.1.0, 2014, First Data Bank, Nutritionist Pro, Axxya Systems, San Bruno, CA). For composite dishes/items that are not included in the USDA database, traditional recipes will be added to the Nutritionist Pro Software, using single food items. ASA24-2016 will be assessed at baseline and Week 12. Caloric intake using the apps will be prompted at Week 4, 8, and 12.

Motivation to lose weight is one of the predictors of successful weight loss programs [82]. Motivation to participate in the trial will be assessed using the Treatment Self-Regulation Questionnaire (TSRQ) [82–84]. TSRQ includes autonomous and controlled regulation subscales. Motivation to participate in the program will be assessed at baseline, Week 4, 8 and 12.

Stages and processes of change in weight management will be assessed using the S-Weight and P-Weight scales [85,86]. The S- and P-Weight scales assess the cognitive predictors of weight change [87]. The S- and P-Weight scales are based on the Transtheoretical model and include stages of change (S-Weight) and processes of change (P-Weight) components to assess the motivation to lose weight, which can be considered both a moderator or a mediator/covariate factor in achieving the main outcome (i.e. weight loss). Stages and processes of change will be assessed at baseline and Week 12.

Prior to the start of the study, all instruments will be piloted with a sample of study participants.

2.5 Recruitment

Upon receiving the approval from the ethics committee, recruitment will start and will be sustained until the minimum number of participants is reached. Considering the challenges to recruitment encountered in the previous study, we will rely on email invitations from the AUB Wellness Program, social media postings using our own social networks, as well as printed posters hung at the University Health Services and other billboards on campus. The research team will seek the help of AUB and AUBMC Communications officers to advertise the study through their social media channels and news websites.

Recruitment Strategies

A. **Emails from AUB Wellness Program.** Invitations to participate in this study will be sent from the AUB Wellness Program to their email distribution lists. The email invitation script is included in Appendix 1.
B. **Posters**. These will be printed and hanged on billboards on campus and possibly posted on monitors on campus TV screens. Sample posters are provided in Appendix 2.
C. **Social media postings.** The study invitations will be also spread on social media using the research team's personal and professional social networks. The postings will include a digital version of the posters. Postings will be shared on Facebook, Instagram, Twitter, LinkedIn, ResearchGate. Samples of social media postings are provided in Appendix 3.

Emails, posters and social media postings will prompt interested participants to visit the University Health Services (UHS) to enquire about the study and enroll, or click on a link leading to an information page.

The landing webpage, available from LimeSurvey, will contain the information about the study and the informed consent. If interested employees will agree, they could complete the eligibility survey online AND visit the University Health Services to complete their enrolment.

2.6 Participant Timeline

2.6.1 Enrolment Phase

Interested employees have to options to enroll:

1) **Online eligibility screener.** The webpage will collect initial consent (Appendix 5), and potential participants will be able to complete a sign-up form and eligibility screener (Appendix 4). At the end of the form they will be instructed to complete their registration by visiting the University Health Services (UHS), where the nurses will verify their eligibility and take basic anthropometric measurements.
2) **UHS visit.** Interested participants will confirm their enrolment in the trial by completing a medical examination with UHS nurses, who will collect height, weight, and waist circumference (these will be used to establish overweight/obesity status). Nurses will fill out a paper-based forms (Appendix 4), cross-checking their qualifications to participate in the study.

If participants are not eligible, nurses will thank them for their interest in the study, but explain they are not eligible for the criteria set by the researchers.

If participants are eligible, nurses will inform the participants the research team will send them a welcome email within one week from the visit. Nurses will provide a hard copy of the consent form (Appendix 5) to all participants.

The research team will visit the University Health Services daily (on week days before 5:00 pm) to collect participant contact information.

Randomization procedures will take place after employees are confirmed to be enrolled in the study.

2.6.2 Intervention Phase

1) **Welcome email.** Within a week from the eligibility visit and randomization, enrolled participants will receive an email with information about the intervention arm they will be assigned. They will receive a link to download the app and will be asked to use the apps for 12 weeks, but their involvement in the study might exceed 13 weeks, from the time they enroll until the time they attend the final visit at the University Health Services. Participants who will be assigned to use *Lark* will be told they will receive a link to download a free Pro version of the app via text message (service provided by Lark Technologies). Participants who will be assigned to use *MyFitnessPal* will receive the link to download the app in the same welcome email. In the welcome email, the research team will also provide a link to the online baseline survey (Appendix 6) and instructions to complete the ASA24-2016 assessment for 3 non-consecutive days, with unique username and passwords (generated by the ASA24-2016 system).
2) **Intermediate emails.** At Week 4 participants will receive an email invitation to complete a first intermediate assessment (collecting data about their weight, perceived app quality, and motivation to lose weight). At Week 8, participants will receive a similar email, which will ask them to complete a second intermediate assessment (weight and motivation to lose weight data). The intermediate questionnaires are provided in Appendix 7.
3) **Final email.** At Week 12, participants will receive an email asking them to complete a final assessment, which will include all study outcomes. The final questionnaire is provided in Appendix 9. The final email will tell participants to visit the UHS to complete the study participation.
4) **Follow-up UHS visit.** At Week 13 follow-up visit, nurses will collect anthropometric measures, hence completing the study.

Reminders. The research team will send up to three reminders for completing each online assessment.

Face-to-face meetings. Participants that require support will contact the study team via a dedicated email, which will be attended by a research assistant. Support face-to-face meetings will follow a standardized script (Appendix 10).

Raffle/Lottery. At the end of the study, a raffle will be conducted. A draw for up to 4 (four) *Fitbit Alta* wristbands will take place at the end of the study (June/July 2018 - the exact date will be notified in due time). The raffle is open to all employees of AUB or AUBMC who enrolled in the study and achieve at least 609 karma points.

Enrolled employees are "those who completed the eligibility screener by providing their contact information". Karma points are awarded for completing the surveys: the online baseline survey is worth **76** WAKpts; each of the three baseline ASA24 food records is worth **50** WAKpts (maximum 150 points); the intermediate surveys (weeks 4 and 8) are worth **41** and **21** points respectively; the final survey is worth **83** points; each of the three final ASA24 food records is worth **100** points (maximum 300 points).

In any draw, chances for winning depends on the number of individuals entering the draw. Given the condition that all enrolled employees can enter the draw, chances for winning one Fitbit are difficult to estimate, since they depend on the number of employees who duly complete the surveys. The research team will carry the draw using a computer-generated random sequence, which will determine up to 5 winners. Winners will be notified via email, which will inform them about the date, time and location to receive their prizes.

Fitbit Alta (worth $129.95, as of September 2017, according to fitbit.com) is a versatile wristband with a display that has a clock and shows the number of steps, calories consumed, and call, text and calendar alerts. The wristband allows uses to automatically track their physical activity, exercise sessions, and sleep. As all other Fitbit products, Alta is synced to a mobile app by Fitbit, which shows the progress towards activity goals, as well as nutrition and sleep patterns.

The research team will send all study participants an email announcing the winners. The email will be sent using the bcc field, so that the recipients of the email will be undisclosed. We will send individualized emails to each winner so that the delivery of the prizes can be arranged.

The study timeline and data collection points are included in Table 1 below.

Table 1. Study Timeline

Activity	Online Eligibility Screener [W0]	Eligibility UHS Visit [W0]	Welcome email [W1]	Baseline assessment [W1]	Mid assessment [W4]	Mid assessment [W8]	Final assessment [W12]	Follow-up UHS Visit [W 13]
Study team procedures								
Consent	X							
Physical Exam (weight, height, waist circumference) and basic demographic information (age, gender)		X						X
Randomization			X					
Study intervention provided			X					
Participant intervention compliance check			X	X	X	X	X	X

Activity	Online Eligibility Screener [W0]	Eligibility UHS Visit [W0]	Welcome email [W1]	Baseline assessment [W1]	Mid assessment [W4]	Mid assessment [W8]	Final assessment [W12]	Follow-up UHS Visit [W 13]
Participant assessments								
Physical activity (IPAQ) [61]				X			X	
Physical activity (steps recorded on phone)					X	X	X	
Dietary assessment (ASA24-2016)				X			X	
Caloric intake (recorded on app)					X	X	X	
Motivation to participate in program TSRQ [83]				X	X	X	X	
Motivation to lose weight [82,86]				X			X	
Weight (recorded on app)					X	X	X	
App quality (uMARS) [39]					X		X	
Feasibility							X	
Acceptability and satisfaction					X	X	X	

2.7 Sample Size

Traditional sample size calculations are not typically undertaken in non-probability sampling and in pilot interventional studies, as these are intended to inform power calculations for subsequent studies. However, it is possible to estimate a minimum sample size required to detect a positive change in the primary outcome (weight) expected to occur in the intervention group, compared to the control. We base our estimates on the average effect size reported in three similar studies with minimal researcher interaction [88–90], included in Schippers et al. [91] meta-analysis of mobile based interventions for weight loss. In these studies, even if they lasted less than 12 weeks, the effect sizes (standardized mean difference based on weight change) were moderate (ranging from d= 0.33 [88], to 0.37 [89]). Using G*Power v3.1 and assuming an alpha level = 0.05 and power = 0.80, a minimum effect size of 0.33 and maximum 0.53, the minimum sample size required to detect a significant mean difference between two independent groups ranges from 114 to 292. With an estimated attrition rate of 30%, we should recruit between 148 and 380 individuals. However, in the absence of similar studies in Lebanon and in the region, and considering that this is a feasibility study, which does not abide to formal sample size calculations [92], as Hertzog suggested [93], we could assume to recruit 50% of the total sample size required for the full trial, which translates into a sample size ranging from 74 to 190 participants.

2.8 Participant Withdrawal or Termination

2.8.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from the study at any time upon informing the principal investigator that they want to conclude their participation in the study. Participants might withdraw if they are diagnosed with a new disease or a medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant. The participant meets an exclusion criterion (either newly developed or not previously recognized) that disqualifies further study participation.

2.8.2 Handling of Participant Withdrawals or Termination

In case of participant withdrawal or termination, the following measures will be taken:

- All data collected regarding the participant prior to withdrawal will remain part of the database and will not be disregarded.
- The withdrawing participant will be asked if they wish to keep providing data and continue follow-up after their withdrawal from the intervention. The participants will be reminded that their confidentiality and privacy will be conserved as before the withdrawal.
- If the participant agrees to continue providing data and undergo follow-ups, then they will have to sign a consent form regarding their limited participation. The IRB must approve the informed consent documents beforehand.
- If the participant does not agree to provide continued follow-up and further data, the participant's confidential records will not be accessed for study purposes. Only data collected prior to withdrawal from the intervention will be reviewed for the study.

2.8.3 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the PI (Dr. Marco Bardus). If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable

Study may resume once concerns about safety, protocol compliance, data quality is addressed and satisfy IRB requirements.

2.9 Assessment of Safety

Behavioral interventions for weight management generally report no adverse events or harms to participants [94,95]. The intervention does not exert any major harm or risk on the participants as the study does not require any treatment or medications that might create a risk to the participants. As this study is focused on using health apps as self-directed intervention, the potential harms may come from carrying out behaviors that are encouraged by the apps. These might include injuries related to physical activity or consequences of an extreme diet. We consider these risks to be very unlikely, as the apps promote dietary self-monitoring and low to moderate intensity activities such as walking. The research team will encourage participants to seek professional help and supervision when planning their diet or activity. Other potential adverse events might be related to psychological factors, elicited by the usage of the app. These may include changes in body satisfaction, appearance and self-worth. In the unlikely case of adverse events, the PI will promptly report to the IRB according to regulatory requirements, as specified in the data safety monitoring plan.

3. Methods: Assignment of Interventions

3.1 Allocation: sequence generation

A random sequence based on minimization procedure will be generated using a computer program, following Altman and Bland's approach [96]. The minimization procedure allows to balance allocation of

study participants to a pre-specified number of treatment groups as soon as they enroll in the study, considering participant characteristics (i.e., stratification by gender, age, and anthropometric features), collected during the eligibility phase. The program used to perform the minimization procedure is OxMaR [97]. A statistician from the Faculty of Health Sciences will generate the sequence using the OxMaR program.

3.2 Allocation concealment

As we need to know how many people have been assigned to use Lark (we need to inform the company, who will provide them access to the pro version of the app), the use of sealed envelopes is not feasible or practical. The research team will inform participants about their allocation after the visit, with the welcome email described above.

3.3 Blinding

Due to the nature of the intervention, participants and research staff cannot be blind to the intervention. However, efforts will be implemented to reduce allocation bias. First, the clinical staff weighing participants at baseline and Week 12 will be blinded to treatment groups. Second, after the baseline clinic visit and the initial account set-up, minimization procedures will be done independently from the PI. Third, the intervention is completely delivered via the mobile apps, completely independent of clinic staff and researchers. The only contact is related to study procedures and data collection. Third, data analysis is conducted on masked data.

4. Methods: Data Collection, Management, and Analysis

4.1 Data Collection Methods

The research material obtained from the eligible enrolled individuals will be mostly of quantitative nature and will be collected through or inputted in online forms.

Nurses will complete a paper-and-pencil eligibility form, which will allow to cross-check the data the participants inputted through LimeSurvey. The eligibility form completed by the nurses will record the anthropometric measurements (height, weight, waist circumference) at baseline and follow-up visits. Research assistants will then input the information in an online form (LimeSurvey). Data entry will be checked by a second research assistant and supervised by the PI.

Participants will complete baseline, intermediate, and follow-up surveys using online forms (LimeSurvey and ASA24-2016, available from the website: https://asa24.nci.nih.gov).

4.2 Data Management

The research team will manage several databases, which will include different participant information. These databases include: a) eligibility screening/sign-up form, b) randomization sequence, c) online surveys (eligibility, baseline, intermediate, and follow-up assessments), d) 24-Hr recall/record, e) app usage.

Eligibility screening database. The PI will oversee the training for entering data collected through the University Health Services on LimeSurvey. The eligibility database will include email as unique identifier, eligibility questions, and comments. Responses will be date stamped and timings will be saved. As data is being entered, a 10% random check will be conducted to cross-examine data entered from the printed forms.

Contact database. From the eligibility database, we will create a contact database, which will include name, surname, email, and mobile phone numbers, which will be used to communicate with study participants. Email address will be used as unique study identifier (study ID), which will be used as matching variable for the other databases. Emails will be used to send participants the link to download the required

apps for the study. The developers will not have access to other participants' contact information. The data will be stored on a password protected hard drive, saved on a password protected AUB computer.

Except for the 24-hr recall/record done through ASA24 online platform, all process and outcome measurements will be collected online through REDCap [44], which is a secure, HIPAA compliant, web-based survey application hosted on AUB servers. REDCap is an ideal program for managing longitudinal studies with multiple assessments.

Randomization sequence database. It will include email address and randomization sequence, generated by the OxMaR software. The sequence will be uploaded on REDCap randomization module.

Baseline, intermediate, and follow-up assessments databases. For each online assessment, a database containing participants' email addresses will be uploaded to REDCap, available from AUB servers. Similar to LimeSurvey, REDCap generates alphanumeric passwords (i.e., tokens) and allows to send emails containing the links to access the surveys. Responses will be date stamped, IP addresses will be logged and timings will be saved. Participants will be allowed to save and resume the survey before submitting it. Once data collection is complete, data will be exported from the online software to Excel to perform data cleaning.

24-Hr recall/record database. ASA24-2016 system allows researchers to upload a list of participant IDs (emails) and the system generates usernames and passwords automatically. The research team will then send participants the system-generated username and password information via email, using Outlook's mail merge feature. Food recall/record data will be stored on the ASA24-2016 servers and will be accessible only by the research team. At the end of the study, data will be downloaded and exported in Excel format.

App usage database. Both *Lark* and *MyFitnessPal* apps constantly collect information about the users' activity (e.g., time spent in the app, number of logins, behavioral check-ins) and allow users to download the data. All study participants assigned to the Lark app will need to consent to its Terms and Conditions before installing it (http://www.web.lark.com/terms-conditions/). Lark will retain the participants' data according to the terms of service outlined in the Privacy Policy, which every user has to approve. Likewise, participants MyFitnessPal, owned by Under Armour, will have to abide to its Privacy Policy (https://account.underarmour.com/privacy?locale=en_en).

Lark has agreed to share with the research team data related to app usage and behavior on weeks 4, 8, and 12, to validate participants' self-reported responses provided using the LimeSurveys.

Lark will not use any contact information of study participants for any purpose, such as marketing or advertising, beyond what is explicitly requested in support of this study. Lark will share data explicitly requested from the study coordinators to assist in the analysis of results, including but not limited to: the "quality" of meals logged, daily activity numbers, weight, sleep duration, and the number of conversations with the Lark coach. *MyFitnessPal* users are allowed to download their data and the developer provides information on how to do so [98,99].

4.2.1 Data Cleaning and Preparation for Analyses

Data cleaning will be performed to remove basic data entry errors and will be completed in Excel. Datasets for analyses will be prepared in SPSS: all cleaned databases will be merged matching the participants' ID (email). Once datasets are merged, the email identifier will be replaced with a unique ID identifier and all identified data will be removed, hence it will not possible to link the final dataset to any of the other databases.

4.2.2 Data Storage

Data collected through Lark is in a secure environment, as required by law and regulations in the United States of America, where Lark is based. Lark is HIPAA compliant and currently undergoing certification for HITRUST, the highest standard of privacy and security for healthcare organizations. MyFitnessPal servers are also secure, as documented in the Under Armour's privacy policy.

All LimeSurvey and REDCap datasets and related applications will be downloaded and stored on a password protected hard drive, saved on a password protected AUB computer, and back-up folders via Dropbox secure servers and maintained up to 3 years.

4.2.3 Data Monitoring

A data monitoring committee, independent from the funding institution, will be formed and will include the PI, co-PI, and an independent statistician working at the Faculty of health Sciences.

The PI will conduct data safety and monitoring, as well as quality control and protocol compliance checks on a weekly basis.

A trained research assistant will complete weekly reports detailing the study progress and subject status, any adverse events, and any protocol deviations. Protocol adherence will be monitored by the Co-PI.

Throughout the study, the PI will review adverse events individually real-time and in aggregate on a monthly basis. The PI will review serious adverse events and intervention complications in real-time. Events determined by the PI to be unanticipated problems involving risks to participants or others will be reported to the IRB within 10 days per policy. Adverse events that are not unanticipated and involving risk to participants or others will be reported per IRB policy at the time of continuing review.

All study staff members will be informed by the PI about any unanticipated problem involving risk to participants and others. If any protocol changes are needed, the PI will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval unless necessary to eliminate apparent immediate hazards to the research participants. In such cases, the IRB will be promptly informed of the change following implementation within 10 working days.

4.3 Statistical considerations

4.3.1 Missing data

Missing data are expected to be minimal for most variables. Where missing values occur, values will be imputed using multiple imputation method using Amelia software [100,101]. If missing data are substantial, a multiple imputation approach will be used with five imputation data sets. Parameters estimates and standard errors across the imputed data sets will be estimated using appropriate formulas provided in King et al. [102] . Missing data bias will be assessed by computing a binary variable reflecting the presence or absence of missing data for each variable in the model and then this binary variable will be correlated with all other variables in the model as well as an array of demographic variables.

4.3.2 Analyses

Data will be summarized using descriptive statistics. Descriptive statistics will be conducted for the overall characteristics of the study population through presenting the numbers and percent for nominal or categorical variables, and means and standard deviations for continuous ones. For variables assessed using multiple items (e.g., uMARS scales), Cronbach's alpha and corrected-item-total correlations will be used to assess the internal consistency of the measured constructs, before aggregating the information (i.e. averaging). Bivariate correlations and chi-square tests will be used to explore associations among demographic and psychographic variables and main study outcomes.

To the best of our knowledge, no formal reliability testing of the uMARS scale have been performed on weight-loss apps. Some measures of reliability – test-retest reliability measured through intraclass-correlation coefficients (ICCs) – were reported in the article describing the development of the uMARS instrument [39]. Reliability of the uMARS scales will be evaluated using both indices of inter-rater agreement (IRA) and inter-rater reliability (IRR) [40,103,104]. Following the recommendations from the literature [105,106], inter-rater agreement (IRA) will be measured according to Brown and Hauenstein's a_{WG} index [107], and the adjusted average deviation index $A_{DM(adj)}$ [108]. IRR indices will be based on intra-class correlation coefficients measuring test-retest reliability [109,110]. Similarly, test-retest reliability

estimates will be used with the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool and the International Physical Activity Questionnaire (short version)[61], whose use has not been reported in the local Lebanese context.

Independent samples t-tests, one-way ANOVAs (or non-parametric alternatives where appropriate) will be used to test differences in the relevant outcome variables (behavioral, cognitive, and weight-related) between intervention groups and between pre- and post-test. Behavioral and weight-related data will be presented using appropriate confidence intervals as suggested by Lee and colleagues [111]. The estimation of efficacy will be based on the observed trends on data over time rather than traditional inferential statistics [112]. Subgroup analyses will include also intent to treat vs. as randomized analyses, to detect whether differences in the outcomes are associated with adherence to the trial (per protocol).

5. Ethics and Dissemination Plans

5.1 Research Ethics Approval

This protocol will be submitted to the approval of the Institutional Review Board (IRB) of the American University of Beirut, section for social and behavioral research studies.

5.2 Consent Procedures

Nurses will collect oral consent from potential trial participants during the first visit and will hand them copies of the informed consent. Research assistants will obtain a signed informed consent at the first face-to-face visit, when participants will be instructed on study procedures and data assessments.

5.3 Confidentiality and Access to Data

Since the target population of this study are employees at the American University of Beirut, they might be considered vulnerable subjects, as the employer might exert power in promoting the study. Personal information will be treated with extreme confidentiality to preserve the privacy of the participants. The research team will not reveal the names of the study participants to their supervisors, nor to other third parties. The app developers will not disclose the information with any one. Data will be presented always in aggregate format. Only the research team will have access to final trial dataset.

5.4 Declaration of interests

Study team members present no financial nor institutional conflict of interest within this study. The PI has contacted the company that developed one of the apps (Lark technologies) to collaborate in the study, but no compensation is foreseen.

The employer (AUB) played any role in the design of this study and will not be involved in the recruitment of the study. Participants will be reminded orally and through the written consent that their participation is completely voluntary and they will incur no penalty should they refuse to participate in or withdraw from the study.

5.5 Protocol amendments

Any changes in the procedures related to recruitment, eligibility criteria, outcomes, analyses, will be implemented and communicated to study participants via email within 2 weeks from the modifications in the protocol.

5.6 Dissemination policy

Results will be communicated in a report for participants. The protocol will be registered in the Clinicaltrials.gov database and a manuscript will be submitted for publication consideration to the leading

eHealth journal (*Journal of Medical Internet Research, JMIR*), in the ancillary journal dedicated to protocols of trials employing mobile and web-related technologies (*JMIR Research Protocols*).

5.7 Authorship eligibility guidelines

Authors will be all research team members if they contributed significantly to the design of the study, drafting and critical revision of manuscripts, data analyses.

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7. Appendices

Appendix 1: Invitation script

Appendix 2: Sample posters advertising the study

Appendix 3: Sample social media post

Appendix 4: Eligibility assessment forms

Appendix 5: Consent form

Appendix 6: Online baseline survey

Appendix 7: Online intermediate surveys

Appendix 8: Online final survey

Appendix 9: Face-to-face meeting script