Consent to participate in WaznApp Research Study

This notice is for an AUB-IRB Approved Research Study for Dr. Marco Bardus and Dr. Ghassan Hamadeh at AUB.

It is not an Official Message from AUB

You are invited to participate in a research study entitled "WaznApp, a self-directed mobile intervention to promote weight control among employees of a Lebanese university" conducted by Dr. Marco Bardus, Faculty of Health Sciences, and Dr. Ghassan Hamadeh, Faculty of Medicine, at the American University of Beirut. The conduct of this study adheres to the IRB approved protocol.

The purpose of the study is to assess the feasibility and preliminary efficacy of a self-directed weight-loss intervention targeting employees of an academic institution, using consumer mobile applications for weight loss. We aim to recruit up to 190 participants.

The IRB approved method for approaching subjects is by posters, email invitation, and social media postings.

This message invites you to read the consent document and consider whether you want to be involved in the study.

What are the qualifications to participate in the study?
To qualify you need to be:
1) An employee of the American University of Beirut (AUB) or its Medical Center (AUBMC).
2) Able to read, write, and understand English.
3) Own a smartphone with either Android (v4.4 or above) with or iOS (v8 or later).
4) Interested in better controlling your weight (i.e., losing weight, preventing weight gain, maintaining weight lost, gaining weight in a healthy way), in order to participate in a 12-week trial aimed at helping you better manage your weight (for example losing weight, preventing weight gain, gaining weight in a healthy way), through the support of mobile apps.

You cannot participate in the study if you: 1) are not employed at AUB or AUBMC; 2) are not able to read, write, and understand English; 3) do not own a smartphone with either Android (v4.4 or above) or iOS (v8 or later); 4) If you are not interested in better controlling your weight.

You cannot participate in the study also if you: have physical disabilities preventing you from exercising or walking; are on a special diet for treatment of chronic conditions (e.g., Diabetes); are diagnosed with anorexia or bulimia nervosa; or if you are under weight loss medications or who have undergone bariatric surgery in the past 3 months.

What will happen if I decide to take part in this research study?
If you volunteer to participate in this study, the researchers will ask you to do the following:

1. **Complete an eligibility screening phase**, which will determine whether you qualify to participate in our study. You will have to fill a brief eligibility survey online then complete a visit at the **University Health Services** (Infirmary, Sawwaf Building). If you are eligible, nurses will measure your height, weight, and waist circumference.
2. **Download/install one of the mobile apps** that you will be assigned to use for 12 weeks. You will receive instructions by email with links to download the apps (free of charge). In case you will need, a research assistant can follow-up with you and ensure that the mobile app is working on your phone.
3. Complete **the following online questionnaires** (*Note: you will receive emails with automatically-generated, personalized links to access all surveys at your convenience*):
    a. **Week 1: Baseline socio-demographic and behavioral questionnaire**, which will assess your socio-demographic characteristics, your physical activity, and your experience with mobile apps for tracking your physical activity, diet or weight.

b. **Week 1: Baseline food recall/record** using the Automated Self-Administered Recall System (ASA24) website. You will be asked to record your foods over 3 non-consecutive days.
c. **Week 4 and Week 8: Intermediate questionnaires**. The surveys serve the purpose to check your progress in the study and evaluate the app that you will be assigned to use.
d. **Week 12**: **Final behavioral questionnaire**, which will include the same questions from the baseline except the socio-demographic. The survey includes also questions about program and app evaluation.
e. **Week 12: Final food recall/record**. You will record your foods over 3 non-consecutive days.

4. Within week 13, complete a **follow-up visit** at the University Health Services (Infirmary, Sawwaf Building), where nurses will measure your height, weight, and waist circumference.

How long will I be in the research study?
Participation in this study will last **12 weeks** from baseline to follow-up assessments. Estimated time for each step is listed below:

- Eligibility screening phase and baseline visit: the completion of the eligibility survey online is 5 minutes, the visit at UHS is estimated to last 15-20 mins max.
- Baseline behavioral questionnaire: The completion of the survey is estimated to last 20-25 minutes.
- Baseline food recall/record: The completion of the survey depends on the type and amount of foods you will eat and enter in the system; it may take 15-20 minutes each day, for 3 non-consecutive days.
- Intermediate questionnaire at Week 4: Estimated time: 15-20 minutes.
- Intermediate questionnaire at Week 8: Estimated time: 10-15 minutes.
- Final behavioral questionnaire: The completion of the survey should take 25-30 minutes.
- Final food recall/record: As for the baseline (15-20 mins/day each of the 3 non-consecutive days).
- Final visit: the nurses should take no more than 5 minutes to take your measurements.

How do I know which application to use throughout the study?
A few days after the visit at UHS, the study team will send you an email to inform you about the app you will be using during the study. The allocation to the different groups of the study will be computer-based and not according to preference.

Are there any potential risks or discomforts that I can expect from this study?
There are no anticipated risks or discomforts. You will be asked to use apps for weight management that are meant to motivate you in eating healthily and engaging in physical activity (walking). The intervention does not pose any major harm or risk as the study does not require any treatment or medications that might create a risk. As this study is focused on using health apps as a 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. We encourage you to seek professional help and supervision (a doctor, a certified dietician or physical education trainer), to develop personalized dietary and activity plans that suit your characteristics and needs.

Are there any potential benefits if I participate?

- The apps used in this study promote physical activity and healthy diet and are intended to assist you in achieving your weight management goals (e.g., weight loss, weight maintenance, weight gain). We believe this might be beneficial for you.
- The whole program is offered free of charge for you. You will use fully-functional versions of the apps, which you will use for the duration of the study.
- If you complete the surveys, you will have the chance to win a wearable device that might motivate you to walk more, eat, and sleep better.
- Also, your active participation in this study will contribute to the advancement of our understanding about the use of mobile apps for weight management and health promotion.

Will I receive any payment if I participate in this study?
You will not receive a payment for your participation in the study. However, you will be awarded "*WaznApp karma points*" (WAKpts) for duly filling the online questionnaires and food records. The points are awarded as follows: the online baseline behavioral questionnaire is worth 76 WAKpts; each of the three baseline

ASA24 food records is worth 50 WAKpts (maximum 150 points); the intermediate questionnaires (weeks 4 and 8) are worth 41 and 21 points, respectively; the final behavioral questionnaire is worth 83 points; each of the three final ASA24 food records is worth 100 points (maximum 300 points). If you obtain at least 600 WAKpts, you will enter the lottery to win a *Fitbit Alta* or *Fitbit Charge 2* wristbands (worth about $130). At the end of the study (June/July 2018), there will be a raffle electing 4 winners. A computer-generated random procedure will be used to identify the winners.

Will information about my participation and me be kept confidential?
The confidentiality of your data will be protected according to current existing Federal laws. Your employer or supervisor will not know that you are participating in this study, unless you wish to share this information with them. Any information will be disclosed only with your permission or as required by law. Please note the following:

- We will use your email address and/or phone number as a way to communicate with you and to send you study-related information, such as unique passwords and usernames for all online secure surveys and food recall/records.
- We will keep a contact database with your personal information, but this will be kept confidential and will not be used in the analyses.
- We will use your email as a unique study identifier to match the responses collected from the different online surveys and app usage. We will not share this information with anyone.
- At the end of the study, when all data will be merged in a unique dataset for the statistical analyses, we will replace your email address with a numeric ID. All contact information will be removed, hence it will not possible to link the final dataset to the original contact database.
- Any paper-based forms that have your name and/or contact information on them will be kept in a locked cabinet in our office that is separate from the databases where the information from the questionnaires and food diaries is stored. Only the principal investigator will have access to the file with your personal information.
- Records will be monitored by the IRB to ensure there will be no breach in confidentiality. Security plans and data use agreements for this project have been approved by AUB and IRB.

What are my rights if I take part in this study?
Participation is voluntary. You can choose whether or not you want to be in this study. Refusal to participate or deciding to withdraw from the study will involve no penalty or loss of benefits to which you are otherwise entitled and neither will it affect their relationship with AUB/AUBMC. If you wish to withdraw, you will have to send an email to the principal investigator, Dr. Marco Bardus (mb141@aub.edu.lb), with the subject "Withdrawal from WaznApp study". The investigator will ask you: 1) if you consent that all data collected through online surveys prior to your withdrawal will remain part of the database, so that it can be used in the analyses; 2) if you wish to keep providing data through online surveys and continue follow-up after your withdrawal from the intervention. Your confidentiality and privacy will be conserved as before the withdrawal. Note that the information you will input in the mobile app will remain on your phone and/or on the servers of the app developer, according to their Terms of Service. If you wish to delete that information, you can simply delete the app.

Withdrawal of participation by the investigator
The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so, in case 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. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made to allow for the full completion of the research study.

Who can answer questions I might have about this study?
If you have any questions, comments or concerns about the research, you can talk to one of the researchers. Please contact Dr. Marco Bardus, principal investigator, mb141@aub.edu.lb, or +961 1 350 000 ext: 4694. In the unlikely event of a research-related injury, please immediately contact the principal investigator.

If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please call the AUB IRB Office: [American University of Beirut, PO BOX: 11-0236 F15, Riad El Solh, Beirut 1107 2020. Tel: 00961 1 374374, ext: 5445. Email: irb@aub.edu.lb]

Please print a copy of this consent form and keep it for your own records.

SIGNATURE OF STUDY PARTICIPANT

I certify that:

- I understand the procedures described above.
- My questions have been answered to my satisfaction, and
- I agree to participate in this study.
- I have been given a copy of this form.

DATE	**SIGNATURE**
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