The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).
Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions
J Med Internet Res 2011;13(4):e126
doi: 10.2196/jmir.1923
PMID: 22209829
* Required
Your name *
First Last

Melinda S. Beder

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
UC San Francisco, San Francisco, California

Your e-mail address *
abc@gmail.com
melinda.bender@ucsf.edu

Title of your manuscript *
Provide the (draft) title of your manuscript.

PilAm Go4Health: A Feasible and Effective Randomized Control Trial Lifestyle Intervention for Filipino Americans

Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

☐ not submitted yet - in early draft status
☐ not submitted yet - in late draft status, just before submission
☐ submitted to a journal but not reviewed yet
☐ submitted to a journal and after receiving initial reviewer comments
☒ submitted to a journal and accepted, but not published yet
☐ published
☐ Other: 

Journal *
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

☐ not submitted yet / unclear where I will submit this
☐ Journal of Medical Internet Research (JMIR)
☒ Other: JMIR - Diabetes

Manuscript tracking number *
If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)
TITLE AND ABSTRACT

1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *
I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

☐ yes
☐ Other: 

1a-i) Identify the mode of delivery in the title
Identify the mode of delivery. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if intervention includes non-web-based Internet components (e.g. email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.

1 2 3 4 5

subitem not at all important ○ ○ □ ○ essential

Does your paper address subitem 1a-i? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

participants eligibility - must own mobile-phone, tablet or computer because part of the intervention study design incorporated participant use of Fitbit Zip and Fitbit app

1a-ii) Non-web-based components or important co-interventions in title
Mention non-web-based components or important co-interventions in title, if any (e.g., “with telephone support”).

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subitem not at all important ○ ○ □ ○ essential
Does your paper address subitem 1a-ii?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

used Fitbit app tracking diary - included in the manuscript but not in the title because title already too long

1a-iii) Primary condition or target group in the title
Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”) Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions
NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT
Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)
Does your paper address subitem 1b-i? *

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Randomized Control Trial Lifestyle Intervention

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

PilAm Go4Health incorporated a Fitbit accelerometer, mobile app/diary health behavior tracking (steps, food/calories, weight) and social media (Facebook) for virtual social support, including seven in-person monthly meetings.

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or “unblinded” to indicated the level of blinding instead of “open”, as “open” in web-based trials usually refers to “open access” (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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subitem not at all important ○ ○ ○ ○ ● essential
Does your paper address subitem 1b-iii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

PilAm Go4Health incorporated a Fitbit accelerometer, mobile app/diary health behavior tracking (steps, food/calories, weight) and social media (Facebook) for virtual social support, including seven in-person monthly meetings.

1b-iv) RESULTS section in abstract must contain use data
Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-iv?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

A total of N=45 FA adults were enrolled and randomized. Mean age was 58+10 years, 62% (28/45) were women,

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials
Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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subitem not at all important  0  0  0  0  essential

Does your paper address subitem 1b-v?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
the intervention had positive results: The PilAm Go4Health was feasible and demonstrated potential efficacy in reducing diabetes risks in overweight Filipino Americans T2D.

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution
Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in “Methods” under 5)


subitem not at all important ○ ○ ○ ○ ☐ essential

Does your paper address subitem 2a-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

conducted a pilot randomized controlled trial (RCT) called the Pilipino (i.e., Filipino) Americans Go4Health (PilAm Go4Health). PilAm Go4Health was an mHealth culturally adapted weight loss lifestyle intervention promoting PA and healthy eating for FA with obesity and T2D to reduce subsequent cardiovascular risks. The purpose of this paper is to report the feasibility of PilAm Go4Health (measured by recruitment, engagement, and retention) and potential efficacy (measured by percent weight and weight (kg) change).

2a-ii) Scientific background, rationale: What is known about the (type of) system
Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.


subitem not at all important ○ ○ ○ ○ ☐ essential
FA have the highest burden and prevalence of obesity and T2D among Asian American subgroups and Non-Hispanic Whites, and have early cardio-metabolic disease risk, with higher mortality rates [4]. Yet, there is limited and incipient preventive health research focused on the FA health disparity [5, 6]. Thus, it is imperative to identify effective interventions to reduce these critical health disparities.

2b) In INTRODUCTION: Specific objectives or hypotheses

The purpose of this paper is to report the feasibility of PilAm Go4Health (measured by recruitment, engagement, and retention) and potential efficacy (measured by percent weight and weight (kg) change). Positive findings will support a follow-on full-scale RCT to test the effectiveness of a culturally adapted mHealth weight loss lifestyle intervention for FA with T2D. Qualitative assessments from participants responses of the PilAm Go4Health acceptability and cultural relevance (measured by process evaluations and post-program interviews) were previously reported [17].

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

This was a pilot RCT of the PilAm Go4Health, a 3-month culturally adapted mHealth weight loss lifestyle intervention for FA with obesity and T2D; followed by a 3-month follow-up maintenance period. This 2-arm trial consisted of an Intervention group and Active Waitlist control (Waitlist) group. Institutional approval from the Committee on Human Research was obtained prior to study implementation. Prior to enrollment, all participants provided written informed consent.

3b) Important changes to methods after trial
Does your paper address CONSORT subitem 3b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

None - no changes made to the methods after trial commencement

3b-i) Bug fixes, Downtimes, Content Changes
Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

Does your paper address subitem 3b-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

none - see above 3b

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
smartphone, tablet or laptop with Internet access; and English language proficient.

Exclusion Criteria. Exclusions included: disabilities precluding walking for 20 minutes; on a special exercise program; participation in a weight loss program participation in the past year; uncontrolled T2D (fasting plasma glucose > 200mg/dl); endocrine or glucose metabolism associated disease (e.g., Cushing’s syndrome or polycystic ovary syndrome); and uncontrolled hypertension. A detailed list of screening and eligibility criteria are reported in a previous publication [18].

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit “de facto” eligibility criterion - this should be explicitly clarified.

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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Participants in the run-in period were asked to wear the Fitbit Zip daily for at least 10 hours/day and send photos of all food and drinks consumed for 3 consecutive days. Those who complied at least 70% of the time with the run-in requirements demonstrated readiness for behaviors change and were enrolled and randomized into the study. Further details on the run-in protocol were previously published [18].

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
Education topics posted by research staff. Participants were encouraged to join the Facebook discussions at least once a week. At this training visit they were given tailored short- and long-term weight loss goals based on participant’s baseline weight, PA, and diet information. Depending on their progress with tailored goals, research staff provided each participant tailored feedback, coaching, and support during research office visits at 1, 2, and 3 months. Table 2 outlines the PilAm Go4Health components delivered at each visit, and weekly Facebook discussion topics posted by research staff.

4a-iii) Information giving during recruitment
Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

Does your paper address subitem 4a-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Institutional approval from the Committee on Human Research was obtained prior to study implementation. Prior to enrollment, all participants provided written informed consent.

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Participants were recruited from the San Francisco Bay Area from December 2014 through December 2015. Recruitment was primarily through word of mouth, community events, and snowball methods. Online recruitment strategies included: San Francisco Bay Area Craigslist (website including classified ads for sale items and services), a dedicated study Facebook website, and an institutional website. Complete recruitment details are published elsewhere [18]. Those who met the screening and eligibility criteria (N=45) were enrolled and randomized into the study (Figure 1. Consort Flow Diagram).

4b-i) Report if outcomes were (self-)assessed through online questionnaires
Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.
Outcome Measures

Primary Outcome. Feasibility was based upon three criteria: recruitment, engagement, and retention. Recruitment goal – have 45 eligible participants recruited, enrolled and randomized for this study. Engagement goal – have participants attend 5 out of 7 intervention office visits (receipt of 9 of the 16 DPP sessions) as a measure for completing the program. This threshold was based on the Center for Disease Control required number of DPP sessions considered for program completion [27]. Retention goal – have at least 80% of randomized participants complete the study as defined by attending 5 of 7 office visits; and complete all required study assessments (physical exams, labs, and surveys) at the baseline, 3-month and 6-month visits.

We monitored adherence to tracking target health behaviors using the Fitbit Zip and Fitbit app/diary. These additional engagement measures described the uptake and acceptance of the PilAm Go4Health program by participants. The criteria for mobile technology tracking by participants were: a) logging weight at least once/week, b) logging daily food/calories at least once/week, and c) wearing Fitbit Zip at least 5 days/week (see Table 4). However, currently there are no standard thresholds for frequency of mHealth app use to evaluate feasibility of an intervention. Any such thresholds would be arbitrary. Therefore, we chose not to use adherence as a measure of engagement to evaluate feasibility.

Secondary Outcome. Percent weight change was used to assess potential efficacy during Phase 1 and 2 for each arm. In Phase 1, the Intervention group received the PilAm Go4Health from baseline to 3-months, while the Waitlist group only used the Fitbit Zip without coaching. In Phase 2, the Waitlist group received the PilAm Go4Health from 3- to 6-months while the Intervention group transitioned to a follow-up maintenance phase.

Other Outcomes. For each arm: 1) change in weight (kg) was measured weekly for 6 months, and 2) change in BMI, waist circumference, fasting plasma glucose, and HbA1c were measured at baseline, 3-months, and 6-months, while daily step-counts were measured in real-time via the Fitbit Zip.

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item – describe only if this may bias results)

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a “Conflict of interest” section or mentioned elsewhere in the manuscript).
Does your paper address subitem 5-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Weekly Facebook discussion topics posted by research staff:

In Phase 2 at the 3-month office visit, Intervention participants transitioned to a 3-month follow-up and were removed from the private Facebook group. Participants were asked to continue using their Fitbit and app/diary to track health behaviors and maintain their weight loss goals. Follow-up office visits were scheduled at 4-month and 6-months. Intervention participants completed the study at 6 months. Further PilAm Go4Health intervention details are reported elsewhere [18].

5-ii) Describe the history/development process
Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

Prior to the study the PilAm Go4Health was culturally tailored for FA according to recommended published cultural adaptation guidelines [22] that include the following 5 components: 1) peripheral, 2) evidential, 3) constituent involving, 4) socio-cultural and 5) linguistic. Examples of each are provided in Table 1. A comprehensive description of the adaptation strategies used in the study are reported in a previous publication [18].

Bender MS, Santos GM, Villanueva C, Arai S. Development of a Mobile Phone-Based Weight Loss Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Protocol and Early Results From the PilAm Go4Health Randomized Controlled Trial. JMIR Res Protoc

5-iii) Revisions and updating
Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).
Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

No components were changed. This is described in the protocol paper previously published at JMIR Research Protocols - see reference below.

Bender MS, Santos GM, Villanueva C, Arai S. Development of a Mobile Phone-Based Weight Loss Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Protocol and Early Results From the PilAm Go4Health Randomized Controlled Trial. JMIR Res Protoc 2016;5(3):e178. PMID: 27608829

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

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subitem not at all important ☐ ☐ ☐ ☜ ☜ essential

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is described in the protocol paper previously published at JMIR Research Protocols - see reference below.

Bender MS, Santos GM, Villanueva C, Arai S. Development of a Mobile Phone-Based Weight Loss Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Protocol and Early Results From the PilAm Go4Health Randomized Controlled Trial. JMIR Res Protoc 2016;5(3):e178. PMID: 27608829

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

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subitem not at all important ☐ ☐ ☐ ☜ ☜ essential

Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
This is described in the protocol paper previously published at JMIR Research Protocols - see reference below

Bender MS, Santos GM, Villanueva C, Arai S. Development of a Mobile Phone-Based Weight Loss Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Protocol and Early Results From the PilAm Go4Health Randomized Controlled Trial. JMIR Res Protoc 2016;5(3):e178. PMID: 27608829

5-vi) Digital preservation
Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 5-vi? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is described in the protocol paper previously published at JMIR Research Protocols - see reference below

Bender MS, Santos GM, Villanueva C, Arai S. Development of a Mobile Phone-Based Weight Loss Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Protocol and Early Results From the PilAm Go4Health Randomized Controlled Trial. JMIR Res Protoc 2016;5(3):e178. PMID: 27608829

5-vii) Access
Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained “access to the platform and Internet” [1]. To ensure access for editors/reviewers/readers, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 5-vii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
no proprietary app by authors were developed or used. Only commercially available device (Fitbit Zip) and Fitbit app were used in this study

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1], whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback” [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

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subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Theoretical Framework
Social cognitive theory and the transtheoretical model for health behavior change helped to guide the study design [20, 21]. According to the social cognitive theory, role models along with socio-cultural and environmental feedback (positive or negative) can influence engagement and adherence to healthy lifestyle behaviors, including healthy eating and physical activity. Social support may also enhance self-efficacy for healthy weight loss behaviors. To enhance social support, PilAm Go4Health incorporated a private Facebook group and...

5-ix) Describe use parameters

Describe use parameters (e.g., intended “doses” and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
Coaching. In Phase 2, the Waitlist group received the Fitbit Zip from 3- to 6-months while the Intervention group transitioned to a follow-up maintenance phase.

Other Outcomes. For each arm: 1) change in weight (kg) was measured weekly for 6 months, and 2) change in BMI, waist circumference, fasting plasma glucose, and HbA1c were measured at baseline, 3-months, and 6-months, while daily step-counts were measured in real-time via the Fitbit Zip.

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as “type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered”. It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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Subitem not at all important 0 0 0 0 1 essential

Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

see all sections 5 above

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

1 2 3 4 5

Subitem not at all important 0 0 0 0 1 essential

Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
5-xii) Describe any co-interventions (incl. training/support)
Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as eHealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

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Subitem not at all important ☐ ☐ ☐ ☐ essential

Does your paper address subitem 5-xii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

none

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

See section 5-ix above
6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

Does your paper address subitem 6a-i?
Copy and paste relevant sections from manuscript text

no online questionnaires were used

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

none used

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

Does your paper address subitem 6a-iii?
6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

None

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size
Describe whether and how expected attrition was taken into account when calculating the sample size.

1 2 3 4 5

subitem not at all important  o  o  o  o  essential

Does your paper address subitem 7a-i?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

none provided in manuscript.

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Randomization
A total of 45 participants were enrolled and randomized in a 1:1 ratio (computer-generated random allocation sequence) then stratified by gender in permuted randomly selected block sizes of 2 and 4 to an intervention group (n=22) or an active Waitlist group (n=23). See Figure 1. Due to the nature of a lifestyle intervention, only the lab technicians and statistician were blinded, but research investigators, staff, and participants were not.

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to
Randomization
A total of 45 participants were enrolled and randomized in a 1:1 ratio (computer-generated random allocation sequence) then stratified by gender in permuted randomly selected block sizes of 2 and 4 to an intervention group (n=22) or an active Waitlist group (n=23). See Figure 1. Due to the nature of a lifestyle intervention, only the lab technicians and statistician were blinded, but research investigators, staff, and participants were not.

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Randomization
A total of 45 participants were enrolled and randomized in a 1:1 ratio (computer-generated random allocation sequence) then stratified by gender in permuted randomly selected block sizes of 2 and 4 to an intervention group (n=22) or an active Waitlist group (n=23). See Figure 1. Due to the nature of a lifestyle intervention, only the lab technicians and statistician were blinded, but research investigators, staff, and participants were not.

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Randomization
A total of 45 participants were enrolled and randomized in a 1:1 ratio (computer-generated random allocation sequence) then stratified by gender in permuted randomly selected block sizes of 2 and 4 to an intervention group (n=22) or an active Waitlist group (n=23). See Figure 1. Due to the nature of a lifestyle intervention, only the lab technicians and statistician were blinded, but research investigators, staff, and participants were not.
11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

**11a-i) Specify who was blinded, and who wasn’t**

Specify who was blinded, and who wasn’t. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☜ essential

**Does your paper address subitem 11a-i?** *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Due to the nature of a lifestyle intervention, only the lab technicians and statistician were blinded, but research investigators, staff, and participants were not.

**11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”**

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☜ essential

**Does your paper address subitem 11a-ii?**

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Due to the nature of a lifestyle intervention, only the lab technicians and statistician were blinded, but research investigators, staff, and participants were not.
11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This was a 2-arm RCT: intervention group and wait-list active control group.

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Statistical Analysis

Descriptive analyses for demographic, clinical, and outcome measures were computed using IBM SPSS for WindowsTM Version 24. Descriptive statistics were obtained by using t-tests, Mann Whitney U, Wilcoxon signed rank tests, or chi-square tests for continuous, non-parametric, or categorical variables as appropriate. Between group differences in percent weight change categories over time were analyzed using a bootstrap chi-square test, including the Mantel-Haenszel test of trend.

The feasibility outcome for recruitment was based upon achieving the target sample size. We reported the simple proportion (%) of participants within each randomized group who met the various target behavior threshold criteria for engagement and retention during the 3-month PilAm Go4Health.

The question for each secondary outcome was whether the change during both study phases was greater for the group receiving the PilAm Go4Health than the non-intervention group. Multilevel regression (aka linear mixed models or hierarchical linear models) was employed to test differences between the two arms in their change trajectories. This effect is also called the cross-level interaction between time and group [28, 29]. In addition to the primary test of between group change, the simple slopes were also tested to determine whether the change was significant within each group.

For these analyses, there were no missing data for the two groups. Therefore, the advantage of the multilevel regression models approach over more traditional repeated measures analysis of variance (when data are missing was not an issue) [28, 29]. However, the use of multilevel regression allowed for the use of bootstrapping when the assumption of normality was not tenable. Bootstrapped Full Information Maximum Likelihood models were estimated to obtain nonparametric, bias-corrected bootstrapped confidence intervals (BC CI) for estimation and inference regarding hypotheses [30-32]. These analyses were carried out with Stata/SE, Version 14 [33, 34]. Primary analysis included intention to treat. Significance was evaluated using a two-sided alpha = .05.

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 12a-i? *
12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Multilevel regression allowed for the use of bootstrapping when the assumption of normality was not tenable. Bootstrapped Full Information Maximum Likelihood models were estimated to obtain nonparametric, bias-corrected bootstrapped confidence intervals (BC CI) for estimation and inference regarding hypotheses [30-32]. These analyses were carried out with Stata/SE, Version 14 [33, 34]. Primary analysis included intention to treat. Significance was evaluated using a two-sided alpha = .05.

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

1  2  3  4  5

subitem not at all important ☐ ☐ ☐ ☐ essential

Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
Institutional approval from the Committee on Human Research was obtained prior to study implementation. Prior to enrollment, all participants provided written informed consent.

x26-ii) Outline informed consent procedures
Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem X26-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

X26-iii) Safety and security procedures
Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem X26-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is described in the protocol paper previously published at JMIR Research Protocols - see reference below

Bender MS, Santos GM, Villanueva C, Arai S. Development of a Mobile Phone-Based Weight Loss Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Protocol and Early Results From the PilAm Go4Health Randomized Controlled Trial. JMIR Res Protoc 2016;5(3):e178. PMID: 27608829
RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Overall participants were categorized as obese with mean BMI 30.1 + 4.6 (Table 3). The only sociodemographic variable with a difference between the two group was “Years lived in the US” (often used as a proxy for acculturation). Although a majority of participants were immigrants, they were highly acculturated (Marin Acculturation Scale [35], mean score=3.5). Since there were no between group differences in acculturation scores, the outcome analyses were not adjusted for years lived in the US.

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Overall participants were categorized as obese with mean BMI 30.1 + 4.6 (Table 3). The only sociodemographic variable with a difference between the two group was “Years lived in the US” (often used as a proxy for acculturation). Although a majority of participants were immigrants, they were highly acculturated (Marin Acculturation Scale [35], mean score=3.5). Since there were no between group differences in acculturation scores, the outcome analyses were not adjusted for years lived in the US.

13b-i) Attrition diagram
Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

subitem not at all important ○ ○ ○ ○ ○ essential
14a) Dates defining the periods of recruitment and follow-up

Participants were recruited from the San Francisco Bay Area from December 2014 through December 2015. Recruitment was primarily through word of mouth, community events, and snowball methods. Online recruitment strategies included: San Francisco Bay Area Craigslist (website including classified ads for sale items and services), a dedicated study Facebook website, and an institutional website. Complete recruitment details are published elsewhere [18]. Those who met the screening and eligibility criteria (N=45) were enrolled and randomized into the study (Figure 1. Consort Flow Diagram).

14a-i) Indicate if critical "secular events" fell into the study period

Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources”

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Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

no critical "secular events" fell into the study period
14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

study was not stopped early

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

See Table 3

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 15-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple “denominators” and provide definitions
Report multiple “denominators” and provide definitions: Report N’s (and effect sizes) “across a range of study participation [and use] thresholds” [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants “used” the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define “use” of the intervention.

Does your paper address subitem 16-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

16-ii) Primary analysis should be intent-to-treat
Primary analysis should be intent-to-treat, secondary analyses could include comparing only “users”, with the appropriate caveats that this is no longer a randomized sample (see 18-i).

Does your paper address subitem 16-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
Data are missing was not an issue) [28, 29]. However, the use of multilevel regression allowed for the use of bootstrapping when the assumption of normality was not tenable. Bootstrapped Full Information Maximum Likelihood models were estimated to obtain nonparametric, bias-corrected bootstrapped confidence intervals (BC CI) for estimation and inference regarding hypotheses [30-32]. These analyses were carried out with Stata/SE, Version 14 [33, 34]. Primary analysis included intention to treat. Significance was evaluated using a two-sided alpha = .05.

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Primary analysis included intention to treat. Significance was evaluated using a two-sided alpha = .05.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use
In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as “average session length”. These must be accompanied by a technical description how a metric like a “session” is defined (e.g., timeout after idle time) [1] (report under item 6a).

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subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 17a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

See Table 5
17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

See Table 5

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

See Table 4, Table 5, and Table 6 and Figure 2

18-i) Subgroup analysis of comparing only users
A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 18-i? 
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
19) All important harms or unintended effects in each group
(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

none - there were no harm or unintended effects to report

19-i) Include privacy breaches, technical problems
Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects” also includes unintended positive effects [2].

[1] [2] [3] [4] [5] subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 19-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

there were no privacy breaches or technical issues to report

19-ii) Include qualitative feedback from participants or observations from staff/researchers
Include qualitative feedback from participants or observations from staff/researchers, if available, on
strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

Does your paper address subitem 19-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Qualitative paper published at:
Maglalang DD, Yoo GJ, Ursua RA, Villanueva C, Chesla CA, Bender MS. "I don't have to explain, people understand": Acceptability and Cultural Relevance of a Mobile Health Lifestyle Intervention for Filipinos with Type 2 Diabetes. Ethn Dis. 2017;27(2):143-54. doi: 10.18865/ed.27.2.143. PubMed PMID: 28439185; PubMed Central PMCID: PMCPMC5398173.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)
Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

Does your paper address subitem 22-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
The PilAm Go4Health was feasible as measured by achieving the recruitment, engagement and retention threshold goals. Results demonstrated potential efficacy of the PilAm Go4Health in reducing weight in FA with overweight and T2D. Each group receiving the PilAm Go4Health program (Intervention group in Phase 1, and Waitlist group in Phase 2) demonstrated significant weight loss, underscoring the PilAm Go4Health potential efficacy. In Phase 1, over half of the intervention participants lost weight. While only 18% (4/22) achieved the overall 5% weight loss goal by 3 months, the weight loss trajectory matched that of...

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ • essential

Does your paper address subitem 22-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

These study findings have practical clinical implications for health providers. As the obesity epidemic grows, health care providers should routinely address the issues of obesity and inactivity that are associated with poor health outcomes. Our results will help inform clinicians about commercially available mHealth tools and social media for patients use to improve health outcomes. Clinicians can tailor patient weight loss goals using these tools to promote engagement and adherence to healthy lifestyle behaviors. In our study, real time feedback from the Fitbit accelerometers along with the associated mHealth app/diary for tracking weight and food/calories may have been an important motivational factor. Utilizing Facebook capabilities for virtual social support among peers in tandem with health education postings may have also influenced improvements in health behavior change [34].

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ • essential

Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
Retention levels and study outcomes since it may have excluded non-compliant potential participants. However, out of 52 potential PilAm Go4Health participants completing the run-in, only 4% (2/52) were categorized as non-compliant (see Figure 1). Furthermore, a recent meta-analysis of interventions in which weight loss was the primary outcome showed studies did not differ significantly in weight loss with or without a run-in period [56], and thus did not compromise generalizability.

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

Does your paper address subitem 21-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Highly educated older FA adults seemed to readily adopt the mobile technology to track health behaviors for diabetes management. The mobile technology used in our study may have influenced adherence to healthy behaviors contributing to weight reduction and improvements in other health outcomes. Further research is needed to evaluate the relative influence of the mHealth components used in the PilAm Go4Health program.

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Clinical Trial registration: ClinicalTrials.gov NCT02290184, https://clinicaltrials.gov/ct2/show/NCT02290184

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *
Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is described in the protocol paper previously published at JMIR Research Protocols - see reference below

Bender MS, Santos GM, Villanueva C, Arai S. Development of a Mobile Phone-Based Weight Loss Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Protocol and Early Results From the PilAm Go4Health Randomized Controlled Trial. JMIR Res Protoc 2016;5(3):e178. PMID: 27608829

25) Sources of funding and other support (such as supply of drugs), role of funders
Does your paper address CONSORT subitem 25? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Acknowledgments
The American Heart Association, NCRP Winter 2014 Mentored Clinical & Population Research Grant Award #14CRP1956008, funded this study. We would like to thank Daniel M. Bender for editing/statistical/tables/figures support for this project, and community stakeholders and members for their important contribution in helping to culturally tailor the intervention and participating in the study.

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated
In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

1 2 3 4 5
subitem not at all important o o o ● essential

Does your paper address subitem X27-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Conflicts of Interest
Authors have no conflicts of interest to declare.

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o yes, major changes
o yes, minor changes
● no

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1.5 hours

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☐ no
☐ Other: possibly

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