ISRCTN16108619 https://doi.org/10.1186/ISRCTN16108619

A mobile health intervention using a smartphone app to improve physical activity in college students

Submission date
09/07/2019

Recruitment status
No longer recruiting

Registration date
06/08/2019

Overall study status
Completed

Last Edited
06/09/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Promotion of healthy lifestyle behaviors among college students is a priority in line with the World Health Organization (WHO) strategies to improve the health through engaging in physical activity (PA). Using mobile health (mHealth) applications (apps) offer a significant potential improvement among college students. The aim of this study is to improve PA (step-counts), and body weight using a theory-based m-Health apps intervention among college students (aged 18-30).

Who can participate?
Healthy college students aged 18-30 years, interested in a healthy lifestyle, and willing to commit the necessary time and effort to participants in the study, with a body mass index (BMI): BMI≥ 18.5, capable of performing ambulatory (walking) physical activity, and who own a Smartphone (iPhone or Android).

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The intervention group receive PA goals in terms of 10,000 steps/day and are informed that this value is roughly equivalent to 30 minutes of walking per day (along with their normal activity). They receive information about the benefits of exercise and instructions on how to use the app. The researcher also demonstrates the usability features of the mobile phone app (using standardized instructions) and encourages this group to use the app to monitor their steps and obtain feedback in order to achieve their target goals. They are also instructed to keep their phones charged and to always carry it during waking hours. By the end of each week (week 2 to week 12), the participants in the intervention group are contacted via SMS/email and are asked to share their step counts data with the researcher. Participants in the control group are provided with information related to daily recommended PA levels (i.e.; 30 minutes daily), and information highlighting the benefits of walking regularly, without being observed or requiring interaction with the researcher. The control group members do not use the pacer app after the first week of assessment phase (baseline assessment) until week 11, until they are contacted for week 12 follow-up assessment, and do not receive any other intervention action.

What are the possible benefits and risks of participating?
This research is important because researchers are interested in the eating and exercise habits of young adults. Participants are introduced to an app that will help them keep track of how many steps they take each day over a 12-week period. While they will not be paid to participate in this study, they will participate in a draw that will give 10 participants a gift card worth $20. Participation in this study is voluntary, and participants may decide not to begin or to stop participating at any time.

Where is the study run from?
Texas A&M University (USA)

When is the study starting and how long is it expected to run for?
September 2017 to August 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Hala Nawaiseh
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
018-0022D

Study information

Scientific Title

An m-health intervention using a smartphone app to improve physical activity in college students: a randomized controlled trial

Acronym
M-Health : Mobile Health

Study objectives
Hypothesis #1: The researchers hypothesized that those using an m-Health lifestyle promoting app (Pacer) will increase PA (step counts) over a 12-week period when compared with the control group. They hypothesized that encouraging students to engage with particular features of an app (e.g.; goal–setting and self-monitoring) will significantly increase their step counts compared to giving standard physical activity (PA) recommendations. The magnitude of change (to reach over 10,000 steps per day) is a clinically significant magnitude and if it continues, is expected to result in long-term health benefits such as reduce cardiovascular and diabetes risks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/02/2018, the IRB at Texas A&M University and the human research ethics committee (Texas A&M University, Human Research Protection Program, 750 Agronomy Road, Suite 2701, TAMU 1186, College Station, TX 77843-1186, USA; Tel: +1 (0)979 458 4067; Email: irb@tamu.edu), ref: IRB2018-0022D

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Physical activity (step counts) among college students

Interventions
The researchers used one of the most popular publicly available smartphone apps for improving the PA (Step counts) (Pacer). It has goal-setting functionality, self-monitoring of step counts, calories expended, and automatic performance feedback through a graphic display of step-count history.

Randomization: Upon completing the baseline assessment, enrolled participants were randomly assigned to intervention group (m- Health app) (n=65) or control group (n=65) in an equal ratio of 1:1. Randomization occurred using random permuted blocks to ensure there were similar numbers of participants in the intervention and control group. The researcher was responsible for generating the allocation sequence using the “Research Randomizer “computer software program available at (www.randomizer.org/form.htm). At the end of week 1, the randomization code was broken by the researcher. Participants understood that two groups existed; however,

they were blinded to the nature of each group. Blinding the researcher was not possible due to the nature of the study, because of the continuous communication between the participants and the researcher during the intervention period.

Intervention Group
The intervention group received PA goals in terms of 10,000 steps/day and was informed that this value is roughly equivalent to 30 minutes of walking per day (along with their normal activity). They received information about the benefits of exercise and instructions on how to use the app. The researcher also demonstrated the usability features of the mobile phone app to the intervention group (using standardized instructions) and encouraged this group to use the app to monitor their steps and obtain feedback, in order to achieve their target goals. They were instructed also to keep their phones charged and to always carry it during waking hours. By the end of each week (week 2 to week 12), the participants in the intervention group were contacted via SMS/email and asked to share their step counts data with the researcher.

Control Group
Participants in the control group were provided with information related to daily recommended PA levels (i.e.; 30 minutes daily), and information highlighting the benefits of walking regularly, without being observed or requiring interaction with the researcher. The control group members did not use the pacer app after the first week of assessment phase (Baseline Assessment) until week 11, until they were contacted for week 12 follow-up assessment, and did not receive any other intervention action.

Intervention Type
Behavioural

Primary outcome(s)
Physical activity means (steps/week) measured using mHealth app-based pedometer (Pacer) at baseline (week 1), week 4, week 8, and week 12

Key secondary outcome(s)
Weight status (body weight, BMI), and body fat percentage assessed using TANITA Body Composition Analyzer (SC331S) at baseline (week 1) and week 12

Completion date
01/08/2018

Eligibility

Key inclusion criteria
1. Healthy college students aged 18-30 years
2. Interested in a healthy lifestyle
3. Willing to commit the necessary time and effort to participants in the study
4. Body mass index (BMI): BMI≥ 18.5
5. Capable of performing ambulatory (walking) physical activity
6. Own a smartphone (iPhone or Android)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
All

Total final enrolment
130

Key exclusion criteria
1. Participants who had no smartphone
2. In another program for weight reduction
3. Pregnancy
4. Lactation
5. Had bariatric or recent surgery
6. Had any of the diagnosed chronic diseases such as musculoskeletal disorders, heart failure, diabetes mellitus, hypertension, dyslipidemia, or cancer
7. Could not undertake moderate exercise for any reason
8. Participants who already used the (Pacer) pedometer app

Date of first enrolment
15/02/2018

Date of final enrolment
15/03/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Texas A&M University
301 Tarrow St
College Station
United States of America
77840

Sponsor information

Organisation
Texas A&M University

ROR
https://ror.org/01f5ytq51

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Hala Nawaiseh (Hala1985@tamu.edu). The data will be available after publishing the data. The data will be released upon the request from the First Author: Hala. Khaled.Nawaiseh and TexasA&M University. The data will be shared and published and consent from the participant is not required.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/06/2022	06/09/2023	Yes	No
Abstract results		02/11/2019	26/11/2021	No	No