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Abstract

Introduction

Obesity and sedentariness are major societal challenges and significant contributors to the global burden of disease and healthcare costs. Information and communication technologies are increasingly being used in interventions to promote behaviour change in diet and physical activity. In particular, social networking platforms seem promising for the delivery of weight control interventions.

We intend to pilot-test an intervention involving the use of a social networking mobile application, and tracking devices (Fitbit Flex 2 and Fitbit Aria scale) to promote the social comparison of weight and physical activity, in order to evaluate whether mechanisms of social influence lead to changes in those outcomes over the course of the study.

Methods and analysis

Mixed methods study involving semi-structured interviews and a pre-post quasi-experimental pilot with one arm, where healthy participants in different body mass index (BMI) categories, aged between 19 and 35 years old, will be subjected to a social networking intervention over a 6-month period. The primary outcome is the average difference in weight before and after the intervention. Secondary outcomes include: body mass index, number of steps per day, engagement with the intervention, social support and system usability. Semi-structured interviews will assess participants' expectations and perceptions regarding the intervention.

Ethics and dissemination

Ethics approval was granted by Macquarie University's Human Research Ethics Committee for Medical Sciences on the 3rd of November of 2016 (ethics reference number 5201600716). The social network will be moderated by a researcher with clinical expertise, who will monitor and respond to concerns raised by participants. Monitoring will involve daily observation of measures collected by the fitness tracker and the wireless scale, as well as continuous supervision of forum interactions and posts. Additionally, a protocol is in place to monitor for participant misbehaviour and direct participants-in-need to appropriate sources of help.

Strengths and limitations

- To the best of our knowledge, this is the first experimental study to evaluate mechanisms of social comparison and weight change in users from different BMI categories, using a mobile social networking application.
- The use of wireless tracking devices to assess weight and physical activity obviates the need to rely on less reliable self-reported measures.
- Qualitative methods will help gather input to optimize the intervention.
- Limitations include the quasi-experimental nature of the study: the pre-post design without randomization hampers the ability to interpret the results, as multiple confounders may be at play.

Introduction

Obesity is a major societal challenge and a significant contributor to the global burden of disease and health care costs[1-3]. Effective weight loss interventions have been identified[4], but weight regain is common in the long term[5,6]. Finding effective ways to promote and sustain weight loss is essential in controlling the obesity epidemic and its health consequences.

Whilst obesity has complex causation, it is clear that diet and exercise patterns play a major role in weight change[5,7]. These lifestyle behaviours are, in turn, strongly shaped by social factors[8-12]. For instance, studies have shown that an individual's likelihood of becoming obese is highly influenced by whether or not someone in their social network becomes obese, suggesting that the norms and behaviours that lead to obesity may indeed propagate in social networks[13]. This suggests the possibility that social networks may similarly be used to spread healthy behaviours and curb the obesity epidemic[14].

Social networks are a particularly interesting system for the delivery of weight management interventions[15]. Social networks are webs of social relationships surrounding individuals[16], that enable several social functions: social influence, social control, social comparison, companionship, and social support[17]. An interesting aspect in social networks is the tendency of people to associate and bond with alike individuals, such as people who share similar interests, beliefs, and behaviours (i.e. homophily)[18]. Additionally, tie strength is a measure of the importance of the interactions between two individuals in a social network. Strong ties are a major source of social support but weaker ties are also crucial, as they seem to be better at transmitting new information and behaviours (a phenomenon known as the "strength of weak ties")[16].

The influence of dissimilar weak ties in weight management remains largely unknown. Until now, most experimental studies in weight management involve samples of relatively homogenous participants (e.g. overweight and/or obese). Furthermore, the effect of different social comparison strategies on motivation to lose weight in heterogeneous groups is still relatively unexplored. Although social comparison has been associated with greater weight loss in weight management interventions[19], it remains a question whether comparisons with higher or lower standards may have different effects on weight. Interestingly, in physical activity studies, social comparison to the level of median performance (50th percentile) has been shown to be more effective in increasing physical activity than anchoring feedback to a higher level such as the top quartile (75th percentile)[20]. A potentially useful way to explore these mechanisms is through the use of online social networks.

Online social networks (OSN), which are now ubiquitous in our lives, enable individuals to create and display a personal profile to other users, as well as to build a network of connections[21]. Moreover, OSNs are increasingly being used for research and public health purposes. Their advantages include the possibility to inexpensively disseminate health interventions, and the ability to create and modify networks specifically for research purposes, a common strategy in network interventions[15].

Given the scale of the obesity 'epidemic' and the need for effective interventions that are simple, affordable and scalable, it is no surprise that social network interventions are emerging as a potentially powerful approach to tackle this health problem[22]. To date, several experiments have been conducted using OSNs to promote weight loss, physical activity and adherence to a healthy diet, with encouraging results[23-26].

Finally, the increasing availability of smartphones, mobile applications (apps), and wireless trackers, such as wearable activity monitors and connected weight scales, is giving rise to new opportunities in the study of weight management and obesity[20,27,28]. Not only do they have the power to reach and be used by individuals at any time in their natural environments, facilitating ongoing real-time tracking, but they also enable the reliable collection of physical activity and anthropometric measures (e.g. weight), thus obviating the need to use less reliable self-reports of these outcomes in research studies[29,30].

This study aims to pilot-test a social networking mobile application connected to wireless tracking devices, in order to evaluate mechanisms of social comparison in users from different BMI categories, as well as to assess effects on BMI, weight and physical activity levels, during 6 months. Qualitative methods will also be used to test the feasibility and acceptance or the intervention, as well to gather input to optimize it, in view of future evaluation in a randomized controlled trial.

Methods and analysis

Study design

We will conduct a mixed methods study involving semi-structured interviews and a pre-post quasi-experimental pilot with one arm, where participants will be subjected to a social networking mobile app intervention over a 6-month period, starting in April 2017 (Figure 1). The study design was chosen to enable efficient testing of the feasibility and acceptance of the intervention, as well to gather input to optimize it and increase its effectiveness. Preliminary exploratory data gathered from this pilot study will also be useful in guiding a future randomized controlled trial. The design of this study followed the 'CONSORT 2010 statement – extension to randomised pilot and feasibility trials'[31].

Study sample and recruitment

Eligible study participants are consenting healthy adults who are able to speak, write and read English, aged between 19 and 35 years old, who plan to be living in Sydney for the duration of the study, own a mobile phone (iOS or Android) with internet access, have Wi-Fi connection at home, are able to use a fitness tracker (Fitbit Flex 2 bracelet) and wireless weight scale (Fitbit Aria scale) for the duration of the study, and agree to have two mobile applications installed on their smartphone (fit.healthy.me and Fitbit). Exclusion criteria include pregnancy or breastfeeding; BMI below 17; prior history of eating disorders; or having diabetes or other co-morbid conditions that might impact on study participation (e.g. severe mental illness, end-stage disease).

Forty participants will be recruited using a purposive sampling technique in order to achieve an equal number of participants for each of the following categories of body mass index (BMI; Kg/m^2): 17-20.9; 21-24.9; 25-29.9; and ≥30. These categories do not directly correspond to the World Health Organization's cut-off points for underweight (<18.5 Kg/m^2), normal weight (18.5-24.9 Kg/m^2), overweight (25-29.9 Kg/m^2) and obese (≥30 Kg/m^2)[32], and were chosen in order to limit the recruitment of people in the lower limits of BMI, who may be at higher risk of becoming severely underweight. The sample size was pragmatically chosen to enable a comprehensive study of the feasibility of the intervention.

The study will be advertised at Macquarie University. The following strategies will be used sequentially until the desired sample size is achieved: 1) posters and flyers will be distributed on campus during 'Orientation week' (i.e. the week that marks the beginning of the academic year in Australia) and onwards; 2) advertisements will be circulated on social media, targeting Macquarie University students and staff; 3) promotional information will be

included in the monthly Macquarie University email newsletter. All of the promotional materials will direct potential participants to the study website, where they will be able to read more information about the study and check the eligibility criteria. The study website will also include a link to a Qualtrics® survey aimed at assessing eligibility criteria. After completing the survey, participants who meet inclusion criteria will be contacted by the research team to schedule a 45-minute session at the study centre.

Intervention

We designed a modular intervention for weight and fitness monitoring (fit.healthy.me) based on the existing Personal Health Record 'Healthy.me'. 'Healthy.me' is a research platform available in web and mobile app versions (iOS, Android), which facilitates the management of health information, communication with health services and peers, and access to decision support and self-care tools[33,34]. Interestingly, its modular development enables the isolation of intervention components in software modules, which can be easily added or removed from the system, and assessed for effectiveness in different combinations. Although the 'complete' Healthy.me system consists of several features that facilitate the self-management of health and health care, fit.healthy.me is focused only on social networking and tracking of weight, BMI and steps (Figure 2).

Several behaviour change techniques were considered in the design of this intervention: self-monitoring and feedback on physical activity, weight and BMI, prompts and cues, social support and social comparison. Prompts and cues (text messages and emails every 2 weeks) were included to remind users to 'wear' the fitness tracker during waking hours and to use the scale daily to monitor their weight, as well as to check fit.healthy.me at least every day.

In all interactions in the system participants may choose to use either a pseudonym or their own name. Furthermore, users are able to interact and provide social support to each other through the use of messaging and the social forum, as well as 'follow' particular 'buddies' with whom they might identify more closely.

In order to enable the automation of self-monitoring, fit.healthy.me was integrated with two digital devices - the Fitbit Flex 2 fitness tracker (bracelet) and the Fitbit Aria weight scale – which wirelessly sync with fit.healthy.me (via the Fitbit Application Programming Interface (API)). Fitbit Flex 2 uses accelerometer technology to measure acceleration signals which are then converted into common indicators of physical activity (e.g. steps) through proprietary

algorithms, and has demonstrated good reliability and validity for measuring step count in free-living conditions[30,35]. Syncing between the Fitbit mobile application and the paired Fitbit Flex 2 occurs periodically throughout the day when the feature 'All-day sync' is turned on. The Fitbit Flex 2 resets to zero at midnight every night; when syncing is not enabled, data is kept on the tracker with minute-to-minute information stored for up to 7 days, and daily information stored for up to 30 days. The Fitbit Aria scale syncs automatically after each weigh-in.

Weight, BMI, and step count measures are obtained by fit.healthy.me from the Fitbit API every 5 minutes. The values for weight and BMI retrieved from the Fitbit API correspond to the last time the person used the weighing scale (independent of the day). In contrast, the value for steps is a daily measure (i.e. it is reset to zero at midnight every day) and the value retrieved from the API by fit.healthy.me at any given point corresponds to the last time the Fitbit Flex 2 bracelet was synced that day.

The social components of the intervention were integrated using a unique social module, which enables users to visualize their step count and weight loss efforts in comparison to other users, through the display of those measures in table and graphical formats (Figure 3).

Mean values for 'Others' and 'Buddies' are calculated automatically by fit.healthy.me using data retrieved from the Fitbit API. In order to enable an objective comparison of each individual with the remaining participants, averages were calculated excluding measures for the 'self'.

Another special consideration was the calculation of mean value for steps. Since observations equal to zero pose a particular problem in accelerometer data (e.g. they may reflect forgetfulness to wear the tracker or non-syncing rather than inactivity[36]) we decided to exclude those observations from the calculation of the mean values for 'Others' and 'Buddies'. This exclusion enables participants to compare themselves at any time with a mean value not skewed by 'zero observations' from individuals not wearing the tracker or not enabling syncing with the API.

Data collection and analysis

Study outcomes

The primary outcome will be the average difference in weight between 6 months and baseline. Secondary outcomes include: body mass index (BMI), number of steps per day,

engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale and fitness tracker were used, number of interactions in the social network), social support and system usability.

For the purposes of assessing the baseline and 6-month measures for the steps count outcome, the mean number of steps per day will be compared between the first and last 7 days of the study, from a minimum of 4 valid days. A valid day was defined as ten or more hours of monitor wear[37]; wear time was defined by subtracting non-wear time from 24 hours, and non-wear was defined as a period of at least 60 consecutive minutes of zero counts, allowing for 1 to 2 minutes of counts between 0 and 100[36].

Qualitative evaluations will occur pre- and post-intervention, with the aim of assessing participants' perspectives regarding the intervention (e.g. usability, feasibility, satisfaction, facilitators and barriers to adherence), as well as to explore potential mechanisms of social comparison and social influence related to this intervention.

Study procedures and data collection

Eligible individuals will be invited to attend an initial 45-minute session at the study centre. During this session, participants will be welcomed into the study, then asked to sign and date a consent form, witnessed by the investigator or another person, and provided with a copy.

Following this, participants' sociodemographic variables will be collected, as well as smartphone usage information (e.g. type of smartphone used, hours per day spent using the smartphone, comfort with using the technology). Participants will also be asked to fill-in two questionnaires: the social support survey[38] and the social network index[39].

Participants will then be asked to answer a few questions about their expectations for the study and anticipated facilitators and barriers in regards to several aspects of the intervention (e.g. use of a wearable to monitor physical activity, daily use of a wireless scale to monitor weight changes, use of the mobile app to track progress, use of the social components of the mobile app). These same aspects will be evaluated again at the end of the intervention.

Finally, baseline measures will be collected (e.g. weight and height). Body weight will be measured to the nearest 0.1 kg in light clothing without shoes using a digital scale (Fitbit Aria scale). Height will be measured to the nearest 0.1 cm at baseline only using a wall-mounted stadiometer. Body mass index (BMI) will be calculated as weight (kg)/height (m^2).

Both the Fitbit mobile app and fit.healthy.me will be downloaded and installed at this point, and a Fitbit account will be created.

Initially, participants will undergo a 7-day period of baseline assessment where they will not be able to login to fit.healthy.me, but will be asked to use the Fitbit Flex 2 every day during waking hours and weigh themselves using the Fitbit Aria scale every day. After this period, participants will be instructed to use both the wireless devices and fit.healthy.me, at least daily.

Both devices will be calibrated previously to the initial study session. Participants will be asked not to use the Fitbit mobile application for the duration of the study period, as it provides several features (e.g. graphical display of physical activity and weight measures through time, goal setting, social comparison, social competition) that could influence study results and limit our ability to assess the effects of fit.healthy.me.

At the end of the 45-minute session, participants will be given the opportunity to ask any questions related to the study protocol or the technology, and will be provided with a telephone number and email address of research personnel for troubleshooting.

Ongoing data collection will include: weight, BMI, number of steps per day, and measures of engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale/tracker was used, number of interactions in the social network). Weight, BMI and step count data, dated and timestamped for each participant, will be retrieved by the research team via the Fitbit API.

At the end of the study, participants will be asked to attend a 30-minute session at the study centre to answer a few questions and provide feedback regarding the intervention. Satisfaction will be measured by administering the System Usability Scale (SUS); scores will be calculated according to Brooke's guidelines[40].

Quantitative data analysis

Outcomes will be compared between baseline and 6-months using independent t tests for continuous variables and Chi-square tests for categorical variables. Mann-Whitney U tests will be used where data are not normally distributed. Sensitivity analyses will explore whether adherence to the intervention influences outcomes. Multivariate analyses will be conducted to explore the effect of adjustment for confounding variables including age, gender, social support, and social network index.

Qualitative data analysis

For the qualitative data analysis, audiotapes will be transcribed verbatim. Content analysis of the qualitative information gathered will be done using NVivo® (NVivo, Melbourne, Australia). Two researchers will systematically review and code the transcripts, following the constant comparative method and thematic analysis[41,42]. Discrepancies in coding between the two investigators will be resolved through consensus. Extracts from the text files will be provided to illustrate each theme or content area.

Ethics and dissemination

Questions or concerns regarding participation will be addressed individually. Participation in the study will be purely voluntary, and participants will have the right to withdraw from participation in this study at any time, without having to give a reason and without adverse consequence.

The social network will be monitored by a research member with clinical expertise, who will respond to concerns raised by participants. Additionally, a protocol will be in place to monitor for participant misbehaviour and direct participants-in-need to appropriate sources of help. Monitoring will involve daily observation of measures collected by the fitness tracker and the wireless scale, as well as continuous supervision of social network interactions and posts.

In the unlikely case that participants mention psychological distress on the forum or experience concerning weight changes, the following procedure will apply: research staff will make a posting on the forum to provide information about where to seek additional help (i.e., seek consultation with general practitioner, attend a nominated counselling service); If a participant reports on the forum that they are experiencing high levels of distress, we will contact the participant informing that they should immediately attend their local hospital emergency department, general practitioner, and/or call Lifeline or 000.

The social features of fit.healthy.me have been previously used in several studies[33,34,43,44]. A button to report any concerns is available to all participants, and displayed after each post in the forum. When this button is used, immediate action is taken by the investigators to contact the participants involved, and provide the necessary support. This protocol has been used in four Healthy.me trials with more than 2000 participants in areas such as influenza vaccination, wellbeing, sexual health, and asthma[33,34,43,44].

Caution will be taken in the handling and storage of the data so that risks to privacy are minimised, in accordance with the Australian Code for the Responsible Conduct of Research. Research data will be held in a secure storage repository at Macquarie University and the electronic data will only be accessible to individual researchers during the time of their involvement in the project. Electronic data will be stored on password-protected computer. No data will be allowed to leave Macquarie University. Hardcopies will be securely stored in a locked cabinet at the Australian Institute of Health Innovation.

Conclusion

We will pilot-test a newly-designed intervention involving the use of a social networking mobile application to promote the social comparison of weight, BMI and physical activity. Ultimately, this study will enable a better understanding of the factors associated with maintaining a healthy weight and being physically active, and the social influences involved in these processes. These results will be important in informing the design of effective, affordable and scalable interventions to tackle the current 'obesity epidemic'.

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Enrolment

Online screener survey

Initial session at the study centre (45 min)
-Informed consent
-Baseline data collection
-Distribution of the fitness tracker and weight scale + instructions
-Setup: fit.healthy.me and Fitbit mobile apps, fitness tracker

Quantitative data collection:
-Sociodemographic variables (date of birth, gender, postcode)
-Weight, height, BMI
-Social support survey
-Social network index
-Smartphone usage

Qualitative data collection:
-Expectations regarding the study
-Anticipated facilitators and barriers to adherence to different aspects of the intervention

Intervention (6 months)

fit.healthy.me social networking mobile app

Features:
-Self-monitoring + feedback + display of physical activity and weight (through integration with wireless weight scale + fitness tracker)
-Prompts and cues (email and text-messaging)
-Social comparison and social support

Ongoing data collection:

-Weight, BMI
-Number of steps/day
-Engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale/tracker was used, number of interactions in the social network)

6-month follow-up

Final session at the study centre (30 min)

-Follow-up data collection

Quantitative data collection:
-Weight, BMI
-Social support survey
-Social network index
-System usability scale

Qualitative data collection:
-Feedback regarding the study and intervention features

Study flowchart

683x936mm (72 x 72 DPI)
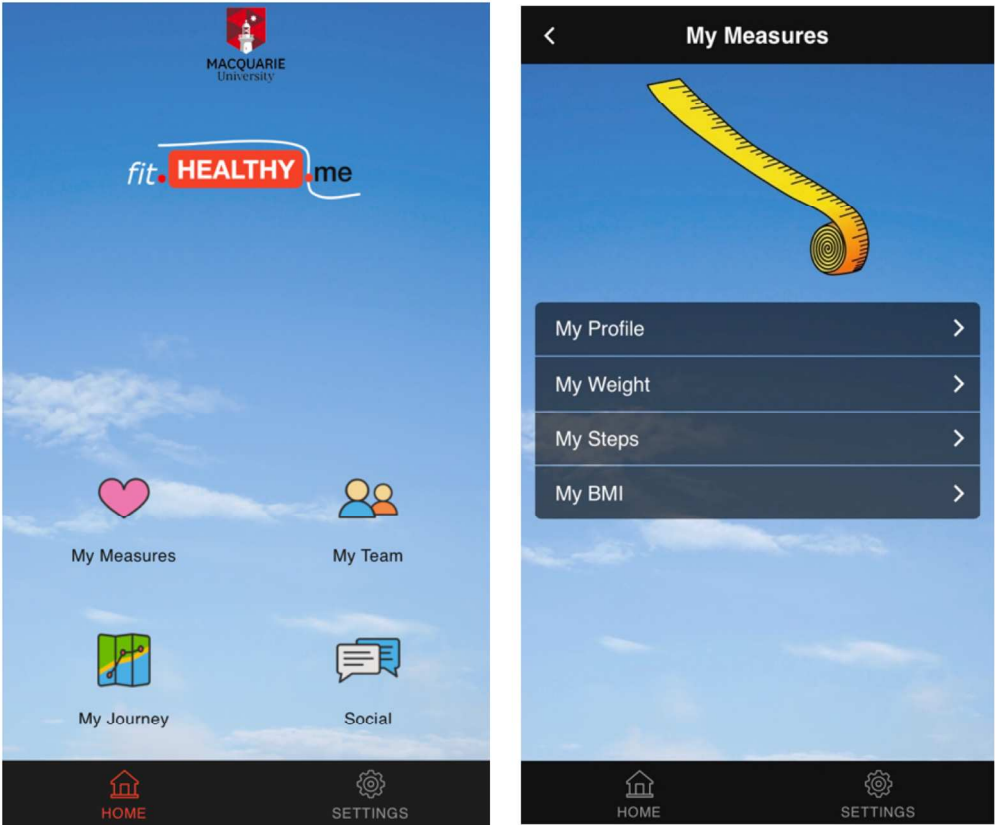
Screenshots of the Home page and 'My measures' module of the fit.healthy.me mobile application

511x422mm (72 x 72 DPI)

BMI	Current	Steps
20.1	**48.3kg**	3677

Current Measures	You	Mean for: Others
Weight (kg)	48.3	63.8
Weight change (kg)	0.0	0.2
BMI	20.1	22.0
Steps	3677	3695

Your step count:
12220
Mean steps for others:
7762

Last Month   All Months   Buddies   Everyone

	Steps
You	12220
Shawn	11871
Ruby	11272
Gary	11192
Robert	10695
Aaron	10119
Theresa	8159
Kath	6743
Ron	6638
Emily	6412
Anthony	2183
Jeremy	100

0   3055   6110   9165   12220   15275
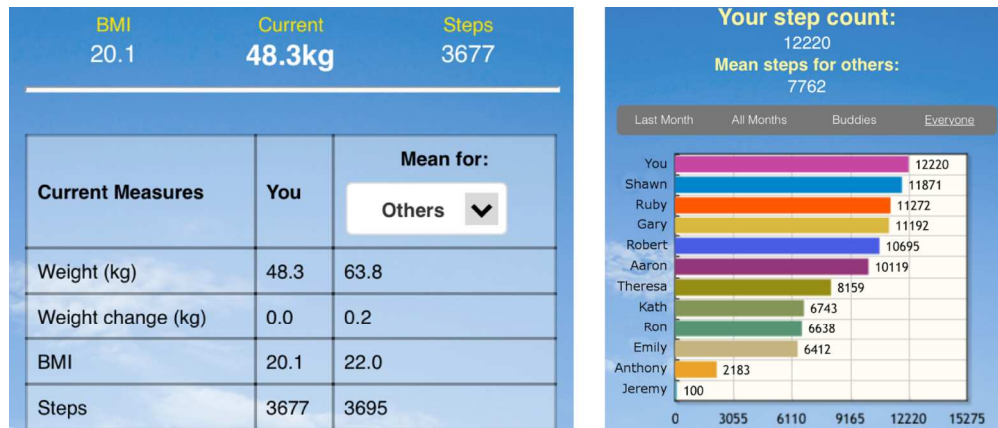
: Screenshots displaying the social comparison features in fit.healthy.me

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Use of a mobile social networking intervention for weight management – a mixed-methods study protocol

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**Use of a mobile social networking intervention for weight management
– a mixed-methods study protocol**

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Abstract

Introduction

Obesity and physical inactivity are major societal challenges and significant contributors to the global burden of disease and healthcare costs. Information and communication technologies are increasingly being used in interventions to promote behaviour change in diet and physical activity. In particular, social networking platforms seem promising for the delivery of weight control interventions.

We intend to pilot-test an intervention involving the use of a social networking mobile application, and tracking devices (Fitbit Flex 2 and Fitbit Aria scale) to promote the social comparison of weight and physical activity, in order to evaluate whether mechanisms of social influence lead to changes in those outcomes over the course of the study.

Methods and analysis

Mixed methods study involving semi-structured interviews and a pre-post quasi-experimental pilot with one arm, where healthy participants in different body mass index (BMI) categories, aged between 19 and 35 years old, will be subjected to a social networking intervention over a 6-month period. The primary outcome is the average difference in weight before and after the intervention. Secondary outcomes include: body mass index, number of steps per day, engagement with the intervention, social support and system usability. Semi-structured interviews will assess participants' expectations and perceptions regarding the intervention.

Ethics and dissemination

Ethics approval was granted by Macquarie University's Human Research Ethics Committee for Medical Sciences on the 3rd of November of 2016 (ethics reference number 5201600716). The social network will be moderated by a researcher with clinical expertise, who will monitor and respond to concerns raised by participants. Monitoring will involve daily observation of measures collected by the fitness tracker and the wireless scale, as well as continuous supervision of forum interactions and posts. Additionally, a protocol is in place to monitor for participant misbehaviour and direct participants-in-need to appropriate sources of help.

Strengths and limitations

- To the best of our knowledge, this is the first experimental study to evaluate mechanisms of social comparison and weight change in users from different BMI categories, using a mobile social networking application.
- The use of wireless tracking devices to assess weight and physical activity obviates the need to rely on less reliable self-reported measures.
- Qualitative methods will help gather input to optimize the intervention.
- Limitations include the quasi-experimental nature of the study: the pre-post design without randomization impacts the interpretation of the results, as multiple confounders may be at play.

Introduction

Obesity is a major societal challenge and a significant contributor to the global burden of disease and health care costs[1][2][3]. Effective weight loss interventions have been identified[4], but weight regain is common in the long term[5][6]. Finding effective ways to promote and sustain weight loss is essential in controlling the obesity epidemic and its health consequences.

Whilst obesity has complex causation, it is clear that diet and physical activity patterns play a major role in weight change[5][7]. These lifestyle behaviours are, in turn, strongly shaped by social factors[8][9][10][11][12]. For instance, studies have shown that an individual's likelihood of becoming obese is highly influenced by whether or not someone in their social network becomes obese, suggesting that the norms and behaviours that lead to obesity may indeed propagate in social networks[13]. This suggests the possibility that social networks may similarly be used to spread healthy behaviours and curb the obesity epidemic[14].

Social networks are a particularly interesting system for the delivery of weight management interventions[15]. Social networks are webs of social relationships surrounding individuals[16], that enable several social functions: social influence, social control, social comparison, companionship, and social support[17]. An interesting aspect in social networks is the tendency of people to associate and bond with alike individuals, such as people who share similar interests, beliefs, and behaviours (i.e. homophily) [18]. Additionally, tie strength is a measure of the importance of the interactions between two individuals in a social network. Strong ties are a major source of social support but weaker ties are also crucial, as they seem to be better at transmitting new information and behaviours (a phenomenon known as the "strength of weak ties") [16].

The influence of dissimilar weak ties in weight management remains largely unknown. Until now, most experimental studies in weight management involve samples of relatively homogenous participants (e.g. overweight and/or obese). Furthermore, the effect of different social comparison strategies on motivation to lose weight in heterogeneous groups is still relatively unexplored. Although social comparison has been associated with greater weight loss in weight management interventions[19], it remains a question whether comparisons with higher or lower standards may have different effects on weight. Interestingly, in physical activity studies, social comparison to the level of median performance (50th percentile) has been shown to be more effective in increasing physical activity than anchoring feedback to a higher level such as the top quartile (75th percentile)[20]. A potentially useful way to explore these mechanisms is through the use of online social networks.

Online social networks (OSN), which are now ubiquitous in our lives, enable individuals to create and display a personal profile to other users, as well as to build a network of connections[21]. Moreover, OSNs are increasingly being used for research and public health purposes. Their advantages include the possibility to inexpensively disseminate health interventions, and the ability to create and modify networks specifically for research purposes, a common strategy in network interventions[15].

Given the scale of the obesity 'epidemic' and the need for effective interventions that are simple, affordable and scalable, it is no surprise that social network interventions are emerging as a potentially powerful approach to tackle this health problem[22]. To date, several experiments have been conducted using OSNs to promote weight loss, physical activity and adherence to a healthy diet, with encouraging results[23][24][25][26]. Nevertheless, research is still needed in order to ascertain how interventions involving OSNs may be optimised to increase their effectiveness[27][28].

Finally, the growing availability of smartphones, mobile applications (apps), and wireless trackers, such as wearable activity monitors and connected weight scales, is giving rise to new opportunities in the study of weight management and obesity[29][30][20]. Not only do they have the power to reach and be used by individuals at any time in their natural environments, facilitating ongoing real-time tracking, but they also enable the reliable collection of physical activity and anthropometric measures (e.g. weight), thus obviating the need to use less reliable self-reports of these outcomes in research studies[31][32].

This study aims to pilot-test a social networking mobile application connected to wireless tracking devices, in order to evaluate mechanisms of social comparison in users from different BMI categories, as well as to assess effects on BMI, weight and physical activity levels, during 6 months. Qualitative methods will also be used to test the feasibility and acceptance or the intervention, as well to gather input to optimize it, in view of future evaluation in a randomized controlled trial.

Methods and analysis

Study design

We will conduct a mixed methods study involving semi-structured interviews and a pre-post quasi-experimental pilot with one arm, where participants will be subjected to a social networking mobile app intervention over a 6-month period, starting in April 2017 (Figure 1). The study design was chosen to enable efficient testing of the feasibility and acceptance of the intervention, as well to gather input to optimize it and increase its effectiveness. Preliminary exploratory data gathered from this pilot study will also be useful in guiding a future randomized controlled trial. The design of this study followed the 'CONSORT 2010 statement – extension to randomised pilot and feasibility trials'[33].

Study sample and recruitment

Eligible study participants are consenting healthy adults who are able to speak, write and read English, aged between 19 and 35 years old, who plan to be living in Sydney for the duration of the study, own a mobile phone (iOS or Android) with internet access, have Wi-Fi connection at home, are able to use a fitness tracker (Fitbit Flex 2 bracelet) and wireless weight scale (Fitbit Aria scale) for the duration of the study, and agree to have two mobile applications installed on their smartphone (fit.healthy.me and Fitbit). Exclusion criteria include pregnancy or breastfeeding; BMI below 17; prior history of eating disorders; or having diabetes or other co-morbid conditions that might impact on study participation (e.g. severe mental illness, end-stage disease).

Forty participants will be recruited using a purposive sampling technique in order to achieve an equal number of participants for each of the following categories of body mass index (BMI; Kg/m^2): 17-20.9; 21-24.9; 25-29.9; and ≥30. These categories do not directly correspond to the World Health Organization's cut-off points for underweight (<18.5 Kg/m^2), normal weight (18.5-24.9 Kg/m^2), overweight (25-29.9 Kg/m^2) and obese (≥30 Kg/m^2)[34], and were chosen in order to limit the recruitment of people in the lower limits of BMI, who may be at higher risk of becoming severely underweight. The sample size was pragmatically chosen to enable a comprehensive study of the feasibility of the intervention.

The study will be advertised at Macquarie University. The following strategies will be used sequentially until the desired sample size is achieved: 1) posters and flyers will be distributed on campus during 'Orientation week' (i.e. the week that marks the beginning of the academic year in Australia) and onwards; 2) advertisements will be circulated on social media, targeting Macquarie University students and staff; 3) promotional information will be

included in the monthly Macquarie University email newsletter. All of the promotional materials will direct potential participants to the study website, where they will be able to read more information about the study and check the eligibility criteria. The study website will also include a link to a Qualtrics® survey aimed at assessing eligibility criteria. After completing the survey, participants who meet inclusion criteria will be contacted by the research team to schedule a 45-minute session at the study centre.

<u>Intervention</u>

We designed a modular intervention for weight and physical activity monitoring (fit.healthy.me) based on the existing Personal Health Record 'Healthy.me'. 'Healthy.me' is a research platform available in web and mobile app versions (iOS, Android), which facilitates the management of health information, communication with health services and peers, and access to decision support and self-care tools[35][36]. Interestingly, its modular development enables the isolation of intervention components in software modules, which can be easily added or removed from the system, and assessed for effectiveness in different combinations. Although the 'complete' Healthy.me system consists of several features that facilitate the self-management of health and health care, fit.healthy.me is focused only on social networking and tracking of weight, BMI and steps (Figure 2).

Several behaviour change techniques were considered in the design of this intervention: self-monitoring and feedback on physical activity, weight and BMI, prompts and cues, social support and social comparison. Prompts and cues (text messages and emails every 2 weeks) were included to remind users to 'wear' the fitness tracker during waking hours and to use the scale daily to monitor their weight, as well as to check fit.healthy.me at least every day.

In all interactions in the system participants may choose to use either a pseudonym or their own name. Furthermore, users are able to interact and provide social support to each other through the use of messaging and the social forum, as well as 'follow' particular 'buddies' with whom they might identify more closely.

In order to enable the automation of self-monitoring, fit.healthy.me was integrated with two digital devices - the Fitbit Flex 2 fitness tracker (bracelet) and the Fitbit Aria weight scale – which wirelessly sync with fit.healthy.me (via the Fitbit Application Programming Interface (API)). Fitbit Flex 2 uses accelerometer technology to measure acceleration signals which are then converted into common indicators of physical activity (e.g. steps) through proprietary

algorithms, and has demonstrated good reliability and validity for measuring step count in free-living conditions[32][37]. Syncing between the Fitbit mobile application and the paired Fitbit Flex 2 occurs periodically throughout the day when the feature 'All-day sync' is turned on. The Fitbit Flex 2 resets to zero at midnight every night; when syncing is not enabled, data is kept on the tracker with minute-to-minute information stored for up to 7 days, and daily information stored for up to 30 days. The Fitbit Aria scale syncs automatically after each weigh-in.

Weight, BMI, and step count measures are obtained by fit.healthy.me from the Fitbit API every 5 minutes. The values for weight and BMI retrieved from the Fitbit API correspond to the last time the person used the weighing scale (independent of the day). In contrast, the value for steps is a daily measure (i.e. it is reset to zero at midnight every day) and the value retrieved from the API by fit.healthy.me at any given point corresponds to the last time the Fitbit Flex 2 bracelet was synced that day.

The social components of the intervention were integrated using a unique social module, which enables users to visualize their step count and weight management efforts in comparison to other users, through the display of those measures in table and graphical formats (Figure 3).

Mean values for 'Others' and 'Buddies' are calculated automatically by fit.healthy.me using data retrieved from the Fitbit API. In order to enable an objective comparison of each individual with the remaining participants, averages were calculated excluding measures for the 'self'.

Another special consideration was the calculation of mean value for steps. Since observations equal to zero pose a particular problem in accelerometer data (e.g. they may reflect forgetfulness to wear the tracker or non-syncing rather than inactivity[38]) we decided to exclude those observations from the calculation of the mean values for 'Others' and 'Buddies'. This exclusion enables participants to compare themselves at any time with a mean value not skewed by 'zero observations' from individuals not wearing the tracker or not enabling syncing with the API.

<u>Data collection and analysis</u>

Study outcomes

The primary outcome will be the average difference in weight between 6 months and baseline. Secondary outcomes include: body mass index (BMI), number of steps per day, engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale and fitness tracker were used, number of interactions in the social network), social support and system usability.

For the purposes of assessing the baseline and 6-month measures for the steps count outcome, the mean number of steps per day will be compared between the first and last 7 days of the study, from a minimum of 4 valid days[38]. A valid day was defined as ten or more hours of monitor wear[37]; wear time was defined by subtracting non-wear time from 24 hours, and non-wear was defined as a period of at least 60 consecutive minutes of zero counts, allowing for 1 to 2 minutes of counts between 0 and 100[39][38].

Qualitative evaluations will occur pre- and post-intervention, with the aim of assessing participants' perspectives regarding the intervention (e.g. usability, feasibility, satisfaction, facilitators and barriers to adherence), as well as to explore potential mechanisms of social comparison and social influence related to this intervention.

Study procedures and data collection

Eligible individuals will be invited to attend an initial 45-minute session at the study centre. During this session, participants will be welcomed into the study, then asked to sign and date a consent form, witnessed by the investigator or another person, and provided with a copy.

Following this, participants' sociodemographic variables will be collected, as well as smartphone usage information (e.g. type of smartphone used, hours per day spent using the smartphone, comfort with using the technology). Participants will also be asked to fill-in two questionnaires: the social support survey[40] and the social network index[41].

Participants will then be asked to answer a few questions about their expectations for the study and anticipated facilitators and barriers in regards to several aspects of the intervention (e.g. use of a wearable to monitor physical activity, daily use of a wireless scale to monitor weight changes, use of the mobile app to track progress, use of the social components of the mobile app). These same aspects will be evaluated again at the end of the intervention.

Finally, baseline measures will be collected (e.g. weight and height). Body weight will be measured to the nearest 0.1 kg in light clothing without shoes using a digital scale (Fitbit Aria scale). Height will be measured to the nearest 0.1 cm at baseline only using a wall-mounted stadiometer. Body mass index (BMI) will be calculated as weight (kg)/height (m^2).

Both the Fitbit mobile app and fit.healthy.me will be downloaded and installed at this point, and a Fitbit account will be created.

Initially, participants will undergo a 7-day period of baseline assessment where they will not be able to login to fit.healthy.me, but will be asked to use the Fitbit Flex 2 every day during waking hours and weigh themselves using the Fitbit Aria scale every day. After this period, participants will be instructed to use both the wireless devices and fit.healthy.me, at least daily. Both devices will be calibrated previously to the initial study session.

At the end of the 45-minute session, participants will be given the opportunity to ask any questions related to the study protocol or the technology, and will be provided with a telephone number and email address of research personnel for troubleshooting.

Ongoing data collection will include: weight, BMI, number of steps per day, and measures of engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale/tracker was used, number of interactions in the social network). Weight, BMI and step count data, dated and timestamped for each participant, will be retrieved by the research team via the Fitbit API.

At the end of the study, participants will be asked to attend a 30-minute session at the study centre to answer a few questions and provide feedback regarding the intervention. Satisfaction will be measured by administering the System Usability Scale (SUS); scores will be calculated according to Brooke's guidelines[42].

Quantitative data analysis

Outcomes will be compared between baseline and 6-months using dependent t tests for continuous variables and Chi-square tests for categorical variables. Wilcoxon signed-rank tests will be used where data are not normally distributed. Sensitivity analyses will explore whether adherence to the intervention influences outcomes. Linear regression analyses will be conducted to explore the effect of multiple predictors and confounding variables, including age, gender, social support, social network index, and daily step count.

Qualitative data analysis

For the qualitative data analysis, audiotapes will be transcribed verbatim. Content analysis of the qualitative information gathered will be done using NVivo® (NVivo, Melbourne, Australia). Two researchers will systematically review and code the transcripts, following the constant comparative method and thematic analysis[43][44]. Discrepancies in coding between the two investigators will be resolved through consensus. Extracts from the text files will be provided to illustrate each theme or content area.

Ethics and dissemination

Questions or concerns regarding participation will be addressed individually. Participation in the study will be purely voluntary, and participants will have the right to withdraw from participation in this study at any time, without having to give a reason and without adverse consequence.

The social network will be monitored by a research member with clinical expertise, who will respond to concerns raised by participants. Additionally, a protocol will be in place to monitor for participant misbehaviour and direct participants-in-need to appropriate sources of help. Monitoring will involve daily observation of measures collected by the fitness tracker and the wireless scale, as well as continuous supervision of social network interactions and posts.

In the unlikely case that participants mention psychological distress on the forum or experience concerning weight changes, the following procedure will apply: research staff will make a posting on the forum to provide information about where to seek additional help (i.e., seek consultation with general practitioner, attend a nominated counselling service); If a participant reports on the forum that they are experiencing high levels of distress, we will contact the participant informing that they should immediately attend their local hospital emergency department, general practitioner, and/or call Lifeline or 000.

The social features of fit.healthy.me have been previously used in several studies[36][35][45][46]. A button to report any concerns is available to all participants, and displayed after each post in the forum. When this button is used, immediate action is taken by the investigators to contact the participants involved, and provide the necessary support. This protocol has been used in four Healthy.me trials with more than 2000 participants in areas such as influenza vaccination, wellbeing, sexual health, and asthma[36][35][45][46].

Caution will be taken in the handling and storage of the data so that risks to privacy are minimised, in accordance with the Australian Code for the Responsible Conduct of Research. Research data will be held in a secure storage repository at Macquarie University and the electronic data will only be accessible to individual researchers during the time of their involvement in the project. Electronic data will be stored on password-protected computer. No data will be allowed to leave Macquarie University. Hardcopies will be securely stored in a locked cabinet at the Australian Institute of Health Innovation.

Authors' contributions: LL, AYSL, PM, HLT and EC developed the protocol, drafted the manuscript, critically revised the manuscript and approve of the final version.

Competing interests: EC and AL could benefit from commercialization of fit.Healthy.me.

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Legends:

Figure 1: Study flowchart

Figure 2: Screenshots of the Home page and 'My measures' module of the fit.healthy.me
mobile application

Figure 3: Screenshots displaying the social comparison features in fit.healthy.me

Enrolment

Online screener survey

Initial session at the study centre (45 min)
-Informed consent
-Baseline data collection
-Distribution of the fitness tracker and weight scale + instructions
-Setup: fit.healthy.me and Fitbit mobile apps, fitness tracker

Quantitative data collection:
-Sociodemographic variables (date of birth, gender, postcode)
-Weight, height, BMI
-Social support survey
-Social network index
-Smartphone usage

Qualitative data collection:
-Expectations regarding the study
-Anticipated facilitators and barriers to adherence to different aspects of the intervention

Intervention (6 months)

fit.healthy.me social networking mobile app

Features:
-Self-monitoring + feedback + display of physical activity and weight (through integration with wireless weight scale + fitness tracker)
-Prompts and cues (email and text-messaging)
-Social comparison and social support

Ongoing data collection:

-Weight, BMI
-Number of steps/day
-Engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale/tracker was used, number of interactions in the social network)

6-month follow-up

Final session at the study centre (30 min)

-Follow-up data collection

Quantitative data collection:
-Weight, BMI
-Social support survey
-Social network index
-System usability scale

Qualitative data collection:
-Feedback regarding the study and intervention features

Study flowchart

299x410mm (300 x 300 DPI)

Screenshots of the Home page and 'My measures' module of the fit.healthy.me mobile application

BMI 20.1	Current **48.3kg**	Steps 3677

Current Measures	You	Mean for: Others
Weight (kg)	48.3	63.8
Weight change (kg)	0.0	0.2
BMI	20.1	22.0
Steps	3677	3695

Your step count:
12220
Mean steps for others:
7762

Last Month	All Months	Buddies	Everyone

You	12220
Shawn	11871
Ruby	11272
Gary	11192
Robert	10695
Aaron	10119
Theresa	8159
Kath	6743
Ron	6638
Emily	6412
Anthony	2183
Jeremy	100

0   3055   6110   9165   12220   15275

Screenshots displaying the social comparison features in fit.healthy.me

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Use of a mobile social networking intervention for weight management – a mixed-methods study protocol

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Use of a mobile social networking intervention for weight management
– a mixed-methods study protocol

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Abstract

Introduction

Obesity and physical inactivity are major societal challenges and significant contributors to the global burden of disease and healthcare costs. Information and communication technologies are increasingly being used in interventions to promote behaviour change in diet and physical activity. In particular, social networking platforms seem promising for the delivery of weight control interventions.

We intend to pilot-test an intervention involving the use of a social networking mobile application, and tracking devices (Fitbit Flex 2 and Fitbit Aria scale) to promote the social comparison of weight and physical activity, in order to evaluate whether mechanisms of social influence lead to changes in those outcomes over the course of the study.

Methods and analysis

Mixed methods study involving semi-structured interviews and a pre-post quasi-experimental pilot with one arm, where healthy participants in different body mass index (BMI) categories, aged between 19 and 35 years old, will be subjected to a social networking intervention over a 6-month period. The primary outcome is the average difference in weight before and after the intervention. Secondary outcomes include: body mass index, number of steps per day, engagement with the intervention, social support and system usability. Semi-structured interviews will assess participants' expectations and perceptions regarding the intervention.

Ethics and dissemination

Ethics approval was granted by Macquarie University's Human Research Ethics Committee for Medical Sciences on the 3rd of November of 2016 (ethics reference number 5201600716). The social network will be moderated by a researcher with clinical expertise, who will monitor and respond to concerns raised by participants. Monitoring will involve daily observation of measures collected by the fitness tracker and the wireless scale, as well as continuous supervision of forum interactions and posts. Additionally, a protocol is in place to monitor for participant misbehaviour and direct participants-in-need to appropriate sources of help.

Strengths and limitations

- To the best of our knowledge, this is the first experimental study to evaluate mechanisms of social comparison and weight change in users from different BMI categories, using a mobile social networking application.

- The use of wireless tracking devices to assess weight and physical activity obviates the need to rely on less reliable self-reported measures.

- Qualitative methods will help gather input to optimize the intervention.

- Limitations include the quasi-experimental nature of the study: the pre-post design without randomization impacts the interpretation of the results, as multiple confounders may be at play.

Introduction

Obesity is a major societal challenge and a significant contributor to the global burden of disease and health care costs[1-3]. Effective weight loss interventions have been identified[4], but weight regain is common in the long term[5,6]. Finding effective ways to promote and sustain weight loss is essential in controlling the obesity epidemic and its health consequences.

Whilst obesity has complex causation, it is clear that diet and physical activity patterns play a major role in weight change[5,7]. These lifestyle behaviours are, in turn, strongly shaped by social factors[8-12]. For instance, studies have shown that an individual's likelihood of becoming obese is highly influenced by whether or not someone in their social network becomes obese, suggesting that the norms and behaviours that lead to obesity may indeed propagate in social networks[13]. This suggests the possibility that social networks may similarly be used to spread healthy behaviours and curb the obesity epidemic[14].

Social networks are a particularly interesting system for the delivery of weight management interventions[15]. Social networks are webs of social relationships surrounding individuals[16], that enable several social functions: social influence, social control, social comparison, companionship, and social support[17]. An interesting aspect in social networks is the tendency of people to associate and bond with alike individuals, such as people who share similar interests, beliefs, and behaviours (i.e. homophily)[18]. Additionally, tie strength is a measure of the importance of the interactions between two individuals in a social network. Strong ties are a major source of social support but weaker ties are also crucial, as they seem to be better at transmitting new information and behaviours (a phenomenon known as the "strength of weak ties")[16].

The influence of dissimilar weak ties in weight management remains largely unknown. Until now, most experimental studies in weight management involve samples of relatively homogenous participants (e.g. overweight and/or obese). Furthermore, the effect of different social comparison strategies on motivation to lose weight in heterogeneous groups is still relatively unexplored. Although social comparison has been associated with greater weight loss in weight management interventions[19], it remains a question whether comparisons with higher or lower standards may have different effects on weight. Interestingly, in physical activity studies, social comparison to the level of median performance (50th percentile) has been shown to be more effective in increasing physical activity than anchoring feedback to a higher level such as the top quartile (75th percentile)[20]. A potentially useful way to explore these mechanisms is through the use of online social networks.

Online social networks (OSN), which are now ubiquitous in our lives, enable individuals to create and display a personal profile to other users, as well as to build a network of connections[21]. Moreover, OSNs are increasingly being used for research and public health purposes. Their advantages include the possibility to inexpensively disseminate health interventions, and the ability to create and modify networks specifically for research purposes, a common strategy in network interventions[15].

Given the scale of the obesity 'epidemic' and the need for effective interventions that are simple, affordable and scalable, it is no surprise that social network interventions are emerging as a potentially powerful approach to tackle this health problem[22]. To date, several experiments have been conducted using OSNs to promote weight loss, physical activity and adherence to a healthy diet, with encouraging results[23-26]. Nevertheless, research is still needed in order to ascertain how interventions involving OSNs may be optimised to increase their effectiveness[27,28].

Finally, the growing availability of smartphones, mobile applications (apps), and wireless trackers, such as wearable activity monitors and connected weight scales, is giving rise to new opportunities in the study of weight management and obesity[20,29,30]. Not only do they have the power to reach and be used by individuals at any time in their natural environments, facilitating ongoing real-time tracking, but they also enable the reliable collection of physical activity and anthropometric measures (e.g. weight), thus obviating the need to use less reliable self-reports of these outcomes in research studies[31,32].

This study aims to pilot-test a social networking mobile application connected to wireless tracking devices, in order to evaluate mechanisms of social comparison in users from different BMI categories, as well as to assess effects on BMI, weight and physical activity levels, during 6 months. Qualitative methods will also be used to test the feasibility and acceptance or the intervention, as well to gather input to optimize it, in view of future evaluation in a randomized controlled trial.

Methods and analysis

Study design

We will conduct a mixed methods study involving semi-structured interviews and a pre-post quasi-experimental pilot with one arm, where participants will be subjected to a social networking mobile app intervention over a 6-month period, starting in April 2017 (Figure 1). The study design was chosen to enable efficient testing of the feasibility and acceptance of the intervention, as well to gather input to optimize it and increase its effectiveness. Preliminary exploratory data gathered from this pilot study will also be useful in guiding a future randomized controlled trial. The design of this study followed the 'CONSORT 2010 statement – extension to randomised pilot and feasibility trials'[33].

Study sample and recruitment

Eligible study participants are consenting healthy adults who are able to speak, write and read English, aged between 19 and 35 years old, who plan to be living in Sydney for the duration of the study, own a mobile phone (iOS or Android) with internet access, have Wi-Fi connection at home, are able to use a fitness tracker (Fitbit Flex 2 bracelet) and wireless weight scale (Fitbit Aria scale) for the duration of the study, and agree to have two mobile applications installed on their smartphone (fit.healthy.me and Fitbit). Exclusion criteria include pregnancy or breastfeeding; BMI below 17; prior history of eating disorders; or having diabetes or other co-morbid conditions that might impact on study participation (e.g. severe mental illness, end-stage disease).

Forty participants will be recruited using a purposive sampling technique in order to achieve an equal number of participants for each of the following categories of body mass index (BMI; Kg/m^2): 17-20.9; 21-24.9; 25-29.9; and ≥30. These categories do not directly correspond to the World Health Organization's cut-off points for underweight (<18.5 Kg/m^2), normal weight (18.5-24.9 Kg/m^2), overweight (25-29.9 Kg/m^2) and obese (≥30 Kg/m^2)[34], and were chosen in order to limit the recruitment of people in the lower limits of BMI, who may be at higher risk of becoming severely underweight. The sample size was pragmatically chosen to enable a comprehensive study of the feasibility of the intervention.

The study will be advertised at Macquarie University. The following strategies will be used sequentially until the desired sample size is achieved: 1) posters and flyers will be distributed on campus during 'Orientation week' (i.e. the week that marks the beginning of the academic year in Australia) and onwards; 2) advertisements will be circulated on social media, targeting Macquarie University students and staff; 3) promotional information will be

included in the monthly Macquarie University email newsletter. All of the promotional materials will direct potential participants to the study website, where they will be able to read more information about the study and check the eligibility criteria. The study website will also include a link to a Qualtrics® survey aimed at assessing eligibility criteria. After completing the survey, participants who meet inclusion criteria will be contacted by the research team to schedule a 45-minute session at the study centre.

Intervention

We designed a modular intervention for weight and physical activity monitoring (fit.healthy.me) based on the existing Personal Health Record 'Healthy.me'. 'Healthy.me' is a research platform available in web and mobile app versions (iOS, Android), which facilitates the management of health information, communication with health services and peers, and access to decision support and self-care tools[35,36]. Interestingly, its modular development enables the isolation of intervention components in software modules, which can be easily added or removed from the system, and assessed for effectiveness in different combinations. Although the 'complete' Healthy.me system consists of several features that facilitate the self-management of health and health care, fit.healthy.me is focused only on social networking and tracking of weight, BMI and steps (Figure 2).

Several behaviour change techniques were considered in the design of this intervention: self-monitoring and feedback on physical activity, weight and BMI, prompts and cues, social support and social comparison. Prompts and cues (text messages and emails every 2 weeks) were included to remind users to 'wear' the fitness tracker during waking hours and to use the scale daily to monitor their weight, as well as to check fit.healthy.me at least every day.

In all interactions in the system participants may choose to use either a pseudonym or their own name. Furthermore, users are able to interact and provide social support to each other through the use of messaging and the social forum, as well as 'follow' particular 'buddies' with whom they might identify more closely.

In order to enable the automation of self-monitoring, fit.healthy.me was integrated with two digital devices - the Fitbit Flex 2 fitness tracker (bracelet) and the Fitbit Aria weight scale – which wirelessly sync with fit.healthy.me (via the Fitbit Application Programming Interface (API)). Fitbit Flex 2 uses accelerometer technology to measure acceleration signals which are then converted into common indicators of physical activity (e.g. steps) through proprietary

algorithms, and has demonstrated good reliability and validity for measuring step count in free-living conditions[32,37]. Syncing between the Fitbit mobile application and the paired Fitbit Flex 2 occurs periodically throughout the day when the feature 'All-day sync' is turned on. The Fitbit Flex 2 resets to zero at midnight every night; when syncing is not enabled, data is kept on the tracker with minute-to-minute information stored for up to 7 days, and daily information stored for up to 30 days. The Fitbit Aria scale syncs automatically after each weigh-in.

Weight, BMI, and step count measures are obtained by fit.healthy.me from the Fitbit API every 5 minutes. The values for weight and BMI retrieved from the Fitbit API correspond to the last time the person used the weighing scale (independent of the day). In contrast, the value for steps is a daily measure (i.e. it is reset to zero at midnight every day) and the value retrieved from the API by fit.healthy.me at any given point corresponds to the last time the Fitbit Flex 2 bracelet was synced that day.

The social components of the intervention were integrated using a unique social module, which enables users to visualize their step count and weight management efforts in comparison to other users, through the display of those measures in table and graphical formats (Figure 3).

Mean values for 'Others' and 'Buddies' are calculated automatically by fit.healthy.me using data retrieved from the Fitbit API. In order to enable an objective comparison of each individual with the remaining participants, averages were calculated excluding measures for the 'self'.

Another special consideration was the calculation of mean value for steps. Since observations equal to zero pose a particular problem in accelerometer data (e.g. they may reflect forgetfulness to wear the tracker or non-syncing rather than inactivity[38]) we decided to exclude those observations from the calculation of the mean values for 'Others' and 'Buddies'. This exclusion enables participants to compare themselves at any time with a mean value not skewed by 'zero observations' from individuals not wearing the tracker or not enabling syncing with the API.

Data collection and analysis

Study outcomes

The primary outcome will be the average difference in weight between 6 months and baseline. Secondary outcomes include: body mass index (BMI), number of steps per day, engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale and fitness tracker were used, number of interactions in the social network), social support and system usability.

For the purposes of assessing the baseline and 6-month measures for the steps count outcome, the mean number of steps per day will be compared between the first and last 7 days of the study, from a minimum of 4 valid days[38]. A valid day was defined as ten or more hours of monitor wear[37]; wear time was defined by subtracting non-wear time from 24 hours, and non-wear was defined as a period of at least 60 consecutive minutes of zero counts, allowing for 1 to 2 minutes of counts between 0 and 100[38,39].

Qualitative evaluations will occur pre- and post-intervention, with the aim of assessing participants' perspectives regarding the intervention (e.g. usability, feasibility, satisfaction, facilitators and barriers to adherence), as well as to explore potential mechanisms of social comparison and social influence related to this intervention.

Study procedures and data collection

Eligible individuals will be invited to attend an initial 45-minute session at the study centre. During this session, participants will be welcomed into the study, then asked to sign and date a consent form, witnessed by the investigator or another person, and provided with a copy.

Following this, participants' sociodemographic variables will be collected, as well as smartphone usage information (e.g. type of smartphone used, hours per day spent using the smartphone, comfort with using the technology). Participants will also be asked to fill-in two questionnaires: the social support survey[40] and the social network index[41].

Participants will then be asked to answer a few questions about their expectations for the study and anticipated facilitators and barriers in regards to several aspects of the intervention (e.g. use of a wearable to monitor physical activity, daily use of a wireless scale to monitor weight changes, use of the mobile app to track progress, use of the social components of the mobile app). These same aspects will be evaluated again at the end of the intervention.

Finally, baseline measures will be collected (e.g. weight and height). Body weight will be measured to the nearest 0.1 kg in light clothing without shoes using a digital scale (Fitbit Aria scale). Height will be measured to the nearest 0.1 cm at baseline only using a wall-mounted stadiometer. Body mass index (BMI) will be calculated as weight (kg)/height (m^2).

Both the Fitbit mobile app and fit.healthy.me will be downloaded and installed at this point, and a Fitbit account will be created.

Initially, participants will undergo a 7-day period of baseline assessment where they will not be able to login to fit.healthy.me, but will be asked to use the Fitbit Flex 2 every day during waking hours and weigh themselves using the Fitbit Aria scale every day. After this period, participants will be instructed to use both the wireless devices and fit.healthy.me, at least daily. Both devices will be calibrated previously to the initial study session.

At the end of the 45-minute session, participants will be given the opportunity to ask any questions related to the study protocol or the technology, and will be provided with a telephone number and email address of research personnel for troubleshooting.

Ongoing data collection will include: weight, BMI, number of steps per day, and measures of engagement with the intervention (i.e. number of logins to fit.healthy.me, number of days the scale/tracker was used, number of interactions in the social network). Weight, BMI and step count data, dated and timestamped for each participant, will be retrieved by the research team via the Fitbit API.

At the end of the study, participants will be asked to attend a 30-minute session at the study centre to answer a few questions and provide feedback regarding the intervention. Satisfaction will be measured by administering the System Usability Scale (SUS); scores will be calculated according to Brooke's guidelines[42].

Quantitative data analysis

Outcomes will be compared between baseline and 6-months using dependent t tests for continuous variables and Chi-square tests for categorical variables. Wilcoxon signed-rank tests will be used where data are not normally distributed. Sensitivity analyses will explore whether adherence to the intervention influences outcomes.

Qualitative data analysis

For the qualitative data analysis, audiotapes will be transcribed verbatim. Content analysis of the qualitative information gathered will be done using NVivo® (NVivo, Melbourne, Australia). Two researchers will systematically review and code the transcripts, following the constant comparative method and thematic analysis[43,44]. Discrepancies in coding between the two investigators will be resolved through consensus. Extracts from the text files will be provided to illustrate each theme or content area.

Ethics and dissemination

Questions or concerns regarding participation will be addressed individually. Participation in the study will be purely voluntary, and participants will have the right to withdraw from participation in this study at any time, without having to give a reason and without adverse consequence.

The social network will be monitored by a research member with clinical expertise, who will respond to concerns raised by participants. Additionally, a protocol will be in place to monitor for participant misbehaviour and direct participants-in-need to appropriate sources of help. Monitoring will involve daily observation of measures collected by the fitness tracker and the wireless scale, as well as continuous supervision of social network interactions and posts.

In the unlikely case that participants mention psychological distress on the forum or experience concerning weight changes, the following procedure will apply: research staff will make a posting on the forum to provide information about where to seek additional help (i.e., seek consultation with general practitioner, attend a nominated counselling service); If a participant reports on the forum that they are experiencing high levels of distress, we will contact the participant informing that they should immediately attend their local hospital emergency department, general practitioner, and/or call Lifeline or 000.

The social features of fit.healthy.me have been previously used in several studies[35,36,45,46]. A button to report any concerns is available to all participants, and displayed after each post in the forum. When this button is used, immediate action is taken by the investigators to contact the participants involved, and provide the necessary support. This protocol has been used in four Healthy.me trials with more than 2000 participants in areas such as influenza vaccination, wellbeing, sexual health, and asthma[35,36,45,46].

Caution will be taken in the handling and storage of the data so that risks to privacy are minimised, in accordance with the Australian Code for the Responsible Conduct of Research. Research data will be held in a secure storage repository at Macquarie University and the electronic data will only be accessible to individual researchers during the time of their involvement in the project. Electronic data will be stored on password-protected computer. No data will be allowed to leave Macquarie University. Hardcopies will be securely stored in a locked cabinet at the Australian Institute of Health Innovation.

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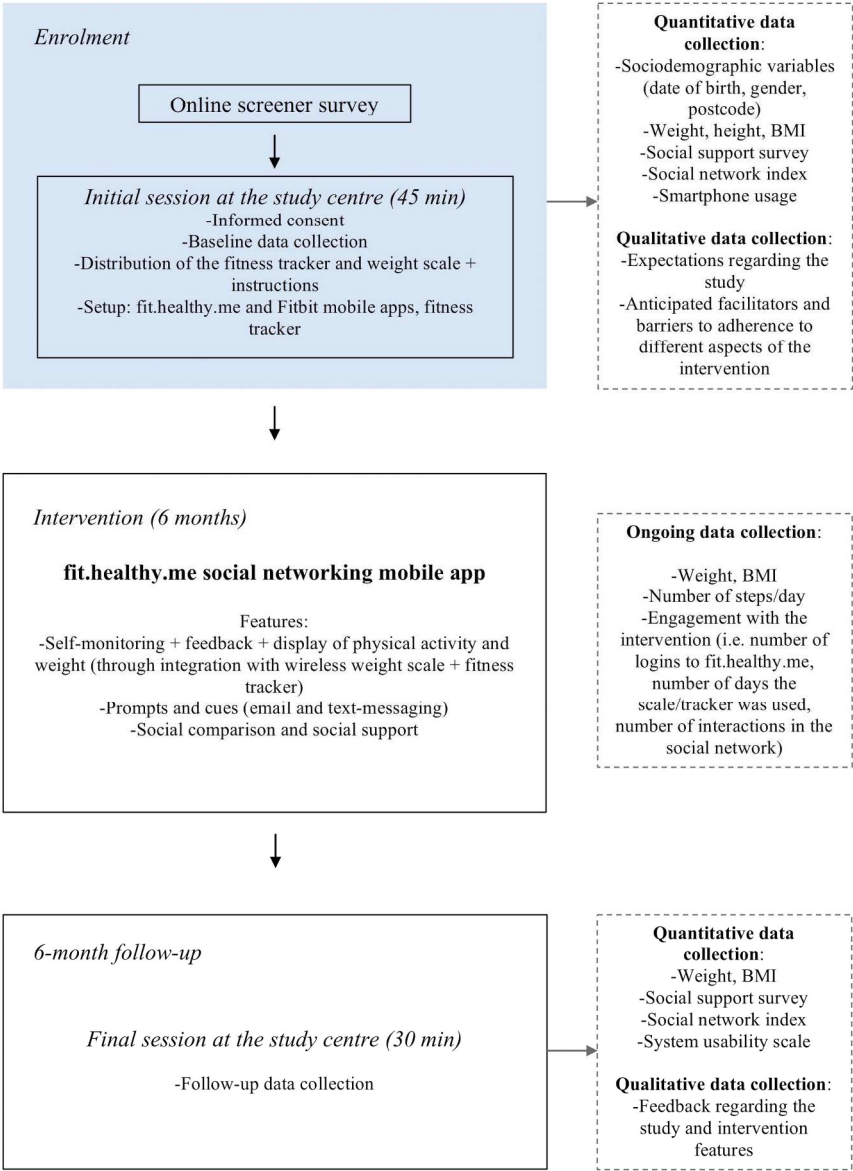
Legends:

Figure 1: Study flowchart

Figure 2: Screenshots of the Home page and 'My measures' module of the fit.healthy.me mobile application

Figure 3: Screenshots displaying the social comparison features in fit.healthy.me

Enrolment

Online screener survey

Initial session at the study centre (45 min)
-Informed consent
-Baseline data collection
-Distribution of the fitness tracker and weight scale +
instructions
-Setup: fit.healthy.me and Fitbit mobile apps, fitness
tracker

**Quantitative data
collection**:
-Sociodemographic variables
(date of birth, gender,
postcode)
-Weight, height, BMI
-Social support survey
-Social network index
-Smartphone usage

Qualitative data collection:
-Expectations regarding the
study
-Anticipated facilitators and
barriers to adherence to
different aspects of the
intervention

Intervention (6 months)

fit.healthy.me social networking mobile app

Features:
-Self-monitoring + feedback + display of physical activity and
weight (through integration with wireless weight scale + fitness
tracker)
-Prompts and cues (email and text-messaging)
-Social comparison and social support

Ongoing data collection:

-Weight, BMI
-Number of steps/day
-Engagement with the
intervention (i.e. number of
logins to fit.healthy.me,
number of days the
scale/tracker was used,
number of interactions in the
social network)

6-month follow-up

Final session at the study centre (30 min)

-Follow-up data collection

**Quantitative data
collection**:
-Weight, BMI
-Social support survey
-Social network index
-System usability scale

Qualitative data collection:
-Feedback regarding the
study and intervention
features

Study flowchart

299x410mm (300 x 300 DPI)

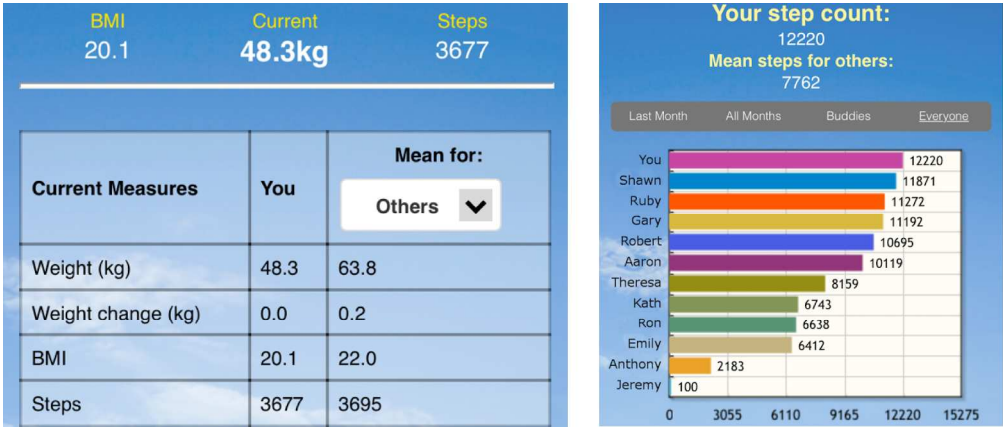Screenshots of the Home page and 'My measures' module of the fit.healthy.me mobile application

	BMI 20.1	Current **48.3kg**	Steps 3677

Current Measures	You	Mean for: Others ▾
Weight (kg)	48.3	63.8
Weight change (kg)	0.0	0.2
BMI	20.1	22.0
Steps	3677	3695

Your step count:
12220
Mean steps for others:
7762

Last Month | All Months | Buddies | Everyone

You	12220
Shawn	11871
Ruby	11272
Gary	11192
Robert	10695
Aaron	10119
Theresa	8159
Kath	6743
Ron	6638
Emily	6412
Anthony	2183
Jeremy	100

0   3055   6110   9165   12220   15275

Screenshots displaying the social comparison features in fit.healthy.me