Submission 003

Queensland University of Technology
Faculty of Health
School of Public Health and Social Work

Victoria Park Road
Kelvin Grove Qld 4059 Australia
Phone [redacted]
www.hlth.qut.edu.au/phsw

Associate Professor Alison L. Marshall, PhD.
NHMRC Career Development Fellow
Institute of Health and Biomedical Innovation
School of Public Health & Social Work
Queensland University of Technology
Victoria Park Road, Kelvin Grove, QLD 4059
t: [redacted] (thur-fri)
e: [redacted]

April 29, 2015

Submission to Queensland Parliament
Health and Ambulance Services Committee

Personal Health Promotion Interventions using Telephone and Web-based Technologies

To whom it may concern,

For over 15 years my team has been developing and evaluating personal health promotion interventions delivered via the Internet and telephone. Our primary aim has always been to reach the most people using the most efficient and effective means possible. This allows our work to have the greatest impact on peoples' health at the lowest cost. Our research has evolved with the changing tide of new communication technologies, and as such we have devoted the last seven years to systematically develop and evaluate health promotion initiatives delivered by **mobile telephone**, in particular, **text messaging.**

Mobile telephone text messaging is the future of health promotion interventions

- There are over 21 million mobile phone subscriptions in Australia [1]
- Over 25% of mobile telephone users have no fixed line service [2]
- Low income homes rely on mobile phone connectivity, as do people who frequently change address [3]
- Three quarters (73%) of mobile phone owners send and receive text-messages [4]
- The reach (scalability) of text message interventions is immense and cost effective [5]

Research consistently demonstrates text-message interventions work

- Qualitative reviews and Meta-analyses consistently conclude that text-message interventions work [2, 6]
- We have demonstrated 20% increase in physical activity guideline compliance following a text-message intervention [7]

Text message interventions are more cost effective than traditional telephone interventions

- Our 2012 Queensland-based research has demonstrated that a 12-week text-message intervention targeting physical activity costs just **$31 per person**. Modeling the observed improvements in health and reductions in health service use resulted in a **cost-effectiveness ratio of $8,608 per quality adjusted life year (QALY)** [5], which is far below the estimated willingness to pay for an additional QALY in Australia of 64,000 AUD [8].
- Our earlier trial conducted in 2008 involving telephone counselling via land line telephones was estimated to cost **$570 per person** over 12 months, with a **cost-effectiveness ratio of $29,375 per QALY** [8].

MobileMums: an effective text message intervention ready for dissemination across Queensland

Our group has systematically developed an effective evidence-based, theory guided text message intervention that assists people to increase their physical activity. The intervention was developed in consultation with end-users and with Queensland Health's Health Practitioner staff. [7, 10]

Briefly, MobileMums is a 12-week intervention initiated with a face-to-face consultation with a behavioural counsellor where; a physical activity goal is set, data for personalising and tailoring subsequent text-messages are collected and a personal MobileMums support person is identified. Clients then receive four to five personally tailored text messages each week via a **custom designed automated software program**.

We have only recently completed an NHMRC funded randomized controlled trial [11] and reported on the interventions efficacy [7] and cost-effectiveness. [5]

We found that our text-message delivered physical activity intervention was;

- feasible to deliver and acceptable to end users [7]
- effective in increasing users physical activity, with an average improvement of 48.5min/wk [7]
- cost effective, it costs just $31 per person to implement and provides better *'bang for buck'* than many other interventions currently provided [5]

The potential for further developing and integrating MobileMums within Queensland Health systems and other virtual operations is vast. My team is keen to work towards Queensland-wide dissemination and evaluation.

I have included the manuscripts written by my team for additional information if required. Please do not hesitate to contact me if you require any further information.

Kind regards

Alison L. Marshall, PhD.
On Behalf of
Alison Marshall, PhD, **Brianna Fjeldsoe,** PhD**, Yvette Miller,** PhD**, Ed Burn,** MSc**, Ashleigh Armanasco,** MIPH**, Nicholas Graves,** PhD**, and Adrian Barnett,** PhD**.**

1.http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/8153.0Main%20Features6December%202014?opendocument&tabname=Summary&prodno=8153.0&issue=December%202014&num=&view=
2. Australian Media and Communications Authority. Communications Report 2013-14. Melbourne, Victoria, Australia: Commonwealth of Australia, 2014.
3. Fjeldsoe BS, Marshall AL, & Miller YD. Behaviour Change Interventions Delivered by Mobile Telephone Short-message Service. *Am J Prev Med* 2009; 36(2): 1650-173.
4. http://www.pewinternet.org/files/old-media//Files/Reports/2011/Americans%20and%20Text%20Messaging.pdf
5. Burn E, Marshall AL, Miller YD, Barnett AG, Fjeldsoe BS, Graves NG. The cost-effectiveness of the *MobileMums* intervention to increase physical activity among mothers with young children: a Markov model informed by a randomised controlled trial. In press BMJ Open.
6. Armanasco A, Miller YD, Fjeldsoe BS, & Marshall AL. Getting the Most out of Text-Message Interventions: Updated review and Meta-Analysis of Preventive Health Behavior Change Interventions. In preparation.
7. Fjeldsoe Miller YD Graves N, Barnett A, Marshall AL. Randomized controlled trial of an improved version of MobileMums, an intervention for increasing physical activity in women with young children. Annals Behav Med, in press.
8. Cadilhac D, Magnus A, Cumming T, et al. *The health and economic benefits of reducing disease risk factors*. Victoria: VicHealth, 2009.
9. Graves N, Barnett A, Halton K, Veerman J, Winkler E, Owen N, Reeves M, Marshall AL, Eakin E. Cost-effectiveness of a telephone-delivered intervention for physical activity and diet. PLos One , 2009. *4(9).*
10. Fjeldsoe BS, Miller YD, O'Brien J, Marshall AL. Iterative development of MobileMums: a physical activity intervention for women with young children. Int J Behav Nutrition Phys Act 2012, 9: 151-162.
11. Marshall AL. Miller YD, Graves N, Barnett A, Fjeldsoe BS. Moving Mobilemums forward: protocol for a larger randomised controlled trial of an improved physical activity program for women with young children. BMC Public Health 2013 13:593.

Queries for Author

Journal: BMJ Open
Paper: bmjopen-2014-007226
Title: The cost-effectiveness of the *MobileMums* intervention to increase physical activity among mothers with young children: a Markov model informed by a randomised controlled trial

The proof of your manuscript appears on the following page(s).

It is the responsibility of the corresponding author to check against the original manuscript and approve or amend these proofs.

Please read the proofs carefully, checking for accuracy, verifying the reference order and checking figures and tables. When reviewing your page proof please keep in mind that a professional copyeditor edited your manuscript to comply with the style requirements of the journal.

This is not an opportunity to alter, amend or revise your paper; it is intended to be for correction purposes only. The journal reserves the right to charge for excessive author alterations or for changes requested after the proofing stage has concluded.

During the preparation of your manuscript for publication, the questions listed below have arisen (the query number can also be found in the gutter close to the text it refers to). Please attend to these matters and return the answers to these questions when you return your corrections.

Please note, we will not be able to proceed with your article if these queries have not been addressed.

A second proof is not normally provided.

Query Reference	Query
Q1	IMPORTANT: Corrections at this stage should be limited to those that are **essential**. Extensive corrections will delay the time to publication and may also have to be approved by the journal Editor.
Q2	Please note that alterations cannot be made after you have approved for publication, irrespective of whether it is Online First.
Q3	Author SURNAMES (family names) have been highlighted - **please check that these are correct**.
Q4	Please check all names are spelt correctly, and check affiliation and correspondence details, including departments.
Q5	Please update volume and page numbers in reference [16].
Q6	Was your article funded by the Research Council UK (eg Medical Research Council), the Wellcome Trust, the Charity of Open Access Fund, or the National Institute for Health Research? Please let us know so we can ensure your article is compliant with your funder's open access policy and the correct license is applied.
Q7	Please check whether the set "Acknowledgements" statement is correct.
Q8	Please check Fjeldsoe *et al* is not matching reference [15].

Author query sheet

If you are happy with the proof as it stands, please email to confirm this. Minor changes that do not require a copy of the proof can be sent by email (please be as specific as possible).
Email: **production.bmjopen@bmj.com**

If you have any changes that cannot be described easily in an email, please mark them clearly on the proof using the annotation tools and email this by reply to the eProof email.

We will keep a copy of any correspondence from you related to the author proof for six months. After six months, correspondence will be deleted.

Please respond within 48 hours

BMJ Open

The cost-effectiveness of the *MobileMums* intervention to increase physical activity among mothers with young children: a Markov model informed by a randomised controlled trial

Edward Burn,[1] Alison L Marshall,[1] Yvette D Miller,[1] Adrian G Barnett,[1] Brianna S Fjeldsoe,[2] Nicholas Graves[1]

To cite: Burn E, Marshall AL, Miller YD, *et al*. The cost-effectiveness of the *MobileMums* intervention to increase physical activity among mothers with young children: a Markov model informed by a randomised controlled trial. *BMJ Open* 2015;**5**:e007226. doi:10.1136/bmjopen-2014-007226

► Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2014-007226).

Received 17 November 2014
Revised 26 February 2015
Accepted 27 February 2015

[1]Queensland University of Technology (QUT), School of Public Health and Social Work and Institute of Health and Biomedical Innovation (IHBI), Brisbane, Queensland, Australia
[2]The University of Queensland, School of Population Health, Brisbane, Queensland, Australia

Correspondence to
Edward Burn;
ea.burn@qut.edu.au

ABSTRACT

Objectives: To determine the cost-effectiveness of the *MobileMums* intervention. *MobileMums* is a 12-week programme which assists mothers with young children to be more physically active, primarily through the use of personalised SMS text-messages.

Design: A cost-effectiveness analysis using a Markov model to estimate and compare the costs and consequences of *MobileMums* and usual care.

Setting: This study considers the cost-effectiveness of *MobileMums* in Queensland, Australia.

Participants: A hypothetical cohort of over 36 000 women with a child under 1 year old is considered. These women are expected to be eligible and willing to participate in the intervention in Queensland, Australia.

Data sources: The model was informed by the effectiveness results from a 9-month two-arm community-based randomised controlled trial undertaken in 2011 and registered retrospectively with the Australian Clinical Trials Registry (ACTRN12611000481976). Baseline characteristics for the model cohort, treatment effects and resource utilisation were all informed by this trial.

Main outcome measures: The incremental cost per quality-adjusted life year (QALY) of *MobileMums* compared with usual care.

Results: The intervention is estimated to lead to an increase of 131 QALYs for an additional cost to the health system of 1.1 million Australian dollars (AUD). The expected incremental cost-effectiveness ratio for *MobileMums* is 8608 AUD per QALY gained. *MobileMums* has a 98% probability of being cost-effective at a cost-effectiveness threshold of 64 000 AUD. Varying modelling assumptions has little effect on this result.

Conclusions: At a cost-effectiveness threshold of 64 000 AUD, *MobileMums* would likely be a cost-effective use of healthcare resources in Queensland, Australia.

Australian Clinical Trials Registry: (ACTRN12611000481976).

Strengths and limitations of this study

- The analysis is informed by the results from a recent two-arm randomised controlled trial of *MobileMums* and usual care.
- Uncertainty around the costs and consequences of *MobileMums* and usual care has been quantified and has little effect on the conclusions of the analysis.
- The model's simplicity, with physical activity levels split into only two categories, means that small changes in an individual's activity would likely not be valued.

INTRODUCTION

Physical inactivity is a leading cause of lost years of healthy life in high-income countries, where chronic diseases are a leading cause of mortality and morbidity.[1] An insufficient level of physical activity, defined as less than 30 min of moderate-intensity to vigorous-intensity physical activity on at least 5 days a week, is directly associated with a number of diseases including coronary heart disease, type 2 diabetes, breast cancer and colon cancer.[2] Physical inactivity is also indirectly linked to the negative health consequences of high body mass and high blood pressure, which include many of the aforementioned chronic conditions.[1]

Fifty-seven per cent of Australia's adult population were insufficiently active in 2011–2012.[3] Begg *et al*[4] estimate that 6.6% of the total disease burden in Australia is caused by physical inactivity, explaining around 24% of cardiovascular disease and diabetes, and around 6% of all cancers. Based on these results, Cadilhac *et al*[5] estimate that each year insufficient physical activity causes 45 000 new cases of disease which are associated

with a loss of 174 000 disability-adjusted life-years in Australia. Inequalities in activity levels exist, with inactivity more likely in older people, those of lower socioeconomic status, those outside of major cities and women.[6] Indeed, women with young children are more likely to be physically inactive than both women with no children[7 8] and women with older children,[9 10] and it is this group who are the focus of the *MobileMums* intervention evaluated here.

The *MobileMums* programme is a 12-week intervention designed to assist women with young children increase their physical activity. The intervention's development has previously been discussed.[11] *MobileMums* is initiated with a face-to-face consultation between the participant and a trained behavioural counsellor. The consultation is used to establish rapport between the participant and counsellor, to gather information required to tailor and personalise text-message content and to initiate the process of behaviour change through personalised goal setting.[11] Participants receive five text-messages per week during weeks 1–4 of the intervention and four text-messages per week during weeks 5–12. The messages are personalised based on the participant's name, the name of their counsellor, the participant's goals and their expected rewards and outcomes for achieving these goals. In addition to receiving the text-messages, participants also have access to a programme handbook, an online exercise directory and a Facebook group. They also receive a refrigerator magnet for self-monitoring and standard information brochures on physical activity. As well as requiring behavioural counsellors, delivering the intervention requires programme coordinators to manage the counsellors, assign participants to a counsellor, oversee the text-messages being sent and received, and to organise sending other programme materials to participants.

In Australia health resources are generally allocated on a state or territory basis[12] and so a decision on whether to fund *MobileMums* would be made by individual states or territories. The alternative course of action would be to provide usual care. The purpose of this paper is to consider this decision of whether to provide *MobileMums* or usual care from the perspective of Queensland Health, the government department responsible for managing the public health system in Queensland, Australia.

It is assumed that the overarching objective of Queensland Health is to maximise population health subject to their budget. This, therefore, supports the need for an economic evaluation of *MobileMums* to consider the intervention's value for money. While this evaluation is specific to the funding decision faced by Queensland Health, it can be expected that the results reported will be directly applicable to similar decisions in other Australian states and territories. The generalisability of the results to other high-income countries may be more limited, for example because of differences in the volume and cost of resource use between countries,[13] but the results are likely to be of relevance for all countries experiencing high levels of physical inactivity.

METHODS

Study population

It is expected that *MobileMums* would be offered to all women with children under 1 year old in Queensland, Australia, regardless of their current level of physical activity. With 61 020 women giving birth in Queensland in 2010 and with 413 fetal deaths,[14] the number of women eligible for the intervention in 2011 was 60 607. We expect around 60% of women who were offered the intervention would participate. This is based on the randomised control trial conducted in 2011,[15 16] where of the 511 women assessed for eligibility 306 started the baseline assessment. This gives 36 364 women in Queensland who would be eligible and willing to participate in the *MobileMums* intervention in 2011, and this is the baseline cohort size considered for this study. This participation estimate of 60% is likely conservative, as the programme would not include the time-consuming assessments that were undertaken purely for research purposes. Given the uncertainty around this estimate, we consider the effects of reducing this cohort size by 50% to 18 182 women, and increasing it by 50% to 54 546 women.

Modelling health outcomes and costs

A state-based Markov model provides the framework for this analysis and is used to estimate the costs and consequences associated with *MobileMums* and usual care. The development of the model has been informed by the effectiveness results from a 9-month two-arm community-based randomised controlled trial undertaken in 2011.[15] A total of 263 women from around Caboolture, Queensland, received usual care (n=130) or the *MobileMums* intervention (n=133).[16] Data were collected prior to the intervention being received (time 1—T1: 0 months), after the 12-week *MobileMums* programme was completed (T2: 3 months) and again after a further 6 month no-contact maintenance period (T3: 9 months). Owing to an administrative error the trial was registered retrospectively with the Australian Clinical Trials Registry (ACTRN12611000481976) and 26 of the trial participants were already receiving *MobileMums* or usual care by the time of registration. However, none of these participants had passed T2 when the trial was registered.

The main efficacy findings from the trial have been reported in detail by Fjeldsoe *et al*.[15] Briefly, while the intervention had a large and statistically significant beneficial effect on activity levels between T1 and T2, there was no statistically significant effect at T3, although the estimated increase in activity remained positive. These results suggest that *MobileMums* can only be expected to have an effect on activity levels in the short-term. Under

the assumption that only long-term changes in activity levels affect the risk of an individual developing future chronic health conditions, the time horizon of the model used is 2 years.

There are just two states in the model with participants either 'physically inactive' or 'physically active', and an individual is required to be undertaking 30 min of moderate-intensity to vigorous-intensity physical activity on at least 5 days a week to be classified as active. An effective physical inactivity intervention increases the likelihood that inactive individuals become active (tpImprove) and/or reduces the likelihood that active individuals become inactive (tpRegress). Individuals move between states using monthly cycles, and spending a month as active or inactive has a cost and health outcome associated with it (described below). An outline of the model is shown in figure 1.

Health effects

To estimate the value for money of *MobileMums*, health effects are expressed in terms of quality-adjusted life-years (QALYs). Given the design of the model used, *MobileMums* can only affect health-related quality-of life, with no mortality effects. The health-related quality-of-life associated with being physically active or inactive was estimated from participants' responses to SF-12 questionnaires at T1, T2 and T3. Mean imputation was used for missing questionnaire data at each time period (1% of participants at T1, 13% at T2, and 32% at T3). Two errors were made in the printing of the SF-12 questionnaires. First, at T1 one question from the SF-12 was omitted in error, and so scores were randomly generated for this dimension. Second, one of the questions offered one too many potential responses at all time periods, and so those who selected this superfluous response were evenly split and moved into either the next best or next worst choice.

Questionnaire responses were transformed into the EQ-5D, a standardised measure of health outcomes, using an algorithm provided by Gray *et al*[17] which provides utility scores close to group means, especially for individuals not in poor health. This approach generates health-related quality-of-life scores associated with spending a year as physically active or inactive which could range between 0 (equivalent to death) and 1 (equivalent to perfect health). Monthly scores were simply one-twelfth of this. QALYs and costs in the second year were discounted at 5% following the relevant guidelines.[18 19]

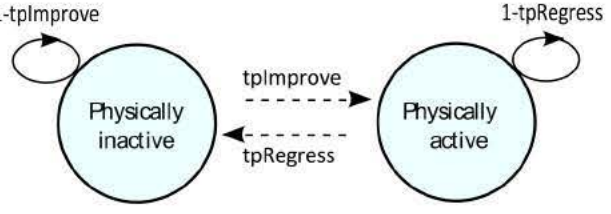


Figure 1 Outline of the Markov model used to estimate the costs and effects of *MobileMums* and usual care.

Costing perspective

This study is intended to inform decision-making regarding resource allocation across the health system in Queensland. Consequently, a health system perspective is taken, with only the costs borne by the health system included.[20] While costs falling outside of the health system, such as the cost to participants of purchasing goods or services related to undertaking exercise, may be of interest, they are not are not of direct relevance given the perspective taken here and so have been excluded. All costs reported have been inflated to 2014 Australian dollars (AUD) and any costs accruing in the second year of the model have been discounted at 5% in line with guidelines for submission to the Medical Services Advisory Committee[18] and the Pharmaceutical Benefits Advisory Committee[19] in Australia.

The estimated cost of providing *MobileMums* across Queensland is based on the costs of delivering the intervention in the randomised controlled trial.[16] To extrapolate these costs, assumptions have been required concerning number of behavioural counsellors and programme coordinators required for widespread dissemination. It is assumed that counsellors could be assigned to 30 participants per week, while coordinators could cover five counsellors and their participants per week. Counsellors and coordinators are assumed to be health practitioners with, on average, 2 years in their current role and, in terms of Queensland Health's salary scale,[21] paid at a HP3 (6092 AUD per month) and a HP4 (8150 AUD per month) level, respectively. The costs of developing the computer programme to send text-messages, sending the text- messages and providing other programme materials are assumed to be the same as in the trial.

In addition to the costs of delivering the intervention, the costs relating to participants healthcare use have also been incorporated. If the intervention reduces future healthcare use then the cost saving associated will counterbalance the cost of providing *MobileMums*. Participants' reported their use of healthcare services at T1, T2 and T3 and the average use of those who were physically active and inactive were estimated. As with the SF-12, mean imputation was used for missing data (0% of participants at T1, 12% at T2, and 31% at T3). The associated costs were estimated using the Medicare Benefits Schedule for July 2011[22] and Australian hospital statistics.[23]

Expected effects

The purpose of this evaluation is to estimate the expected value for money of the *MobileMums* intervention, which is indicated by the incremental cost-effectiveness ratio (ICER) for *MobileMums*. This ratio is given by the expected (mean) change in costs associated with the intervention divided by the expected change in

QALYs.[24] This ratio can then be compared against a cost-effectiveness threshold. The threshold used is 64 000 AUD which is based on the estimate by Shiroiwa *et al*[25] of the willingness-to-pay for an additional QALY in Australia. If the cost-effectiveness ratio for *MobileMums* falls below 64 000 AUD then the intervention can be expected to be 'cost-effective'.

Uncertainty

Parameter uncertainty was quantified using Monte Carlo simulations, with the model evaluated 10 000 times, with each simulation involving random draws from each parameter distribution. These distributions are based on the trial data, with transition probabilities and QALYs given beta distributions, while healthcare utilisation and its associated costs assigned γ distributions and uniform distributions, respectively. This produces 10 000 pairs of incremental costs and effects, and these are presented on a cost-effectiveness plane along with the expected costs and effects and the cost-effectiveness threshold. The probability that *MobileMums* is cost-effective is given by the proportion of pairs of incremental costs and benefits at which the intervention would be considered cost-effective. The percentage of pairs where the change in QALYs is positive and the change in costs is negative is equal to the probability that *MobileMums* is cost-saving. It is also possible to estimate credible intervals around the expected change in costs and QALYs by taking percentiles of the costs and QALYs produced in the Monte Carlo analysis.[26]

Uncertainty also exists surrounding the modelling assumptions. In particular, three areas stand out for particularly onerous assumptions: transition probabilities after 9 months (T3), the number of programme counsellors and coordinators required, and the number of women who would be eligible and willing to participate in the trial. The assumptions used for these areas are the subject of scenario analyses. First, the model is reassessed under the assumption that after T3 all programme activity effects are mitigated entirely, and then again under the assumption that the estimated treatment effect observed at T3 is maintained for a further 15 months, at which point the treatment effect is entirely mitigated. Second, the number of counsellors and coordinators required is increased by 50% and reduced by 50%. And lastly, increasing the cohort size by 50% and reducing it by 50% is considered.

RESULTS

Average effects

The input variables are detailed in table 1. Around 70% of the women entering the model at T1 are expected to be physically inactive. Under usual care there is a small and gradual expected positive net movement from inactive to active over time, and after 24 months around 35% of the initial cohort are expected to be in the active state. The expected effect of *MobileMums* is to cause a substantial increase in physical activity over the duration of the 12-week intervention, with 50% of the participants expected to be in the active state at T2. Following the intervention gradual reduction in the proportion of active participants each month is expected, until after 16 months whereby the effect of *MobileMums* has been mitigated entirely. These expected changes in activity levels are presented in figure 2.

Table 1 Input variables for the Markov model

	Mean	SE	Distribution
Probability of being inactive at T1	0.71	0.03	β
Probability of moving from inactive to active (tpImprove)			
Usual Care (T1 to T2)	0.20	0.04	β
MobileMums (T1 to T2)	0.35	0.05	β
Usual Care (T2 to T3)	0.14	0.04	β
MobileMums (T2 to T3)	0.26	0.05	β
Probability of moving from active to inactive (tpRegress)			
Usual Care (T1 to T2)	0.43	0.08	β
MobileMums (T1 to T2)	0.18	0.06	β
Usual Care (T2 to T3)	0.33	0.07	β
MobileMums (T2 to T3)	0.45	0.06	β
Monthly healthcare utilisation costs (2014 AUD per participant)			
Physically active	53.30	39.20	Uniform and γ*
Physically inactive	75.40	32.62	Uniform and γ*
Cost of delivering *MobileMums* (2014 AUD per participant)	62.64	13.08	Uniform
EQ5D score			
Inactive	0.78	0.01	β
Active	0.81	0.01	β

*A uniform distribution for healthcare costs and a gamma distribution for healthcare utilisation.
AUD, Australian dollar.

Time spent in the active state is expected to provide slightly higher utility than time spent in the inactive state, with a year spent as physically active associated with a health-related quality-of-life score of 0.81 compared with 0.78 for a year spent as physically inactive. As *MobileMums* is expected to increase the total number of months spent by the cohort in the active state, the intervention can therefore also be expected to improve health-related quality-of-life. Over 24 months, *MobileMums* is estimated to lead to an increase of 131 QALYs across the cohort of 36 364 women or, equivalently, 0.0036 QALYs per person.

The expected cost of delivering *MobileMums* to the cohort is 2 277 950 AUD, or 63 AUD per person. The breakdown for this cost is shown in table 2. Almost half the cost is due to the behavioural counsellors. While there are significant costs associated with setting up the programme, such as the development of a computer programme to send personalised text-messages, these costs are of little consequence with a cohort of 36 364 women.

Based on data from the trial it is estimated that active individuals cost the health system 53 AUD a month on average, while inactive individuals cost 75 AUD per

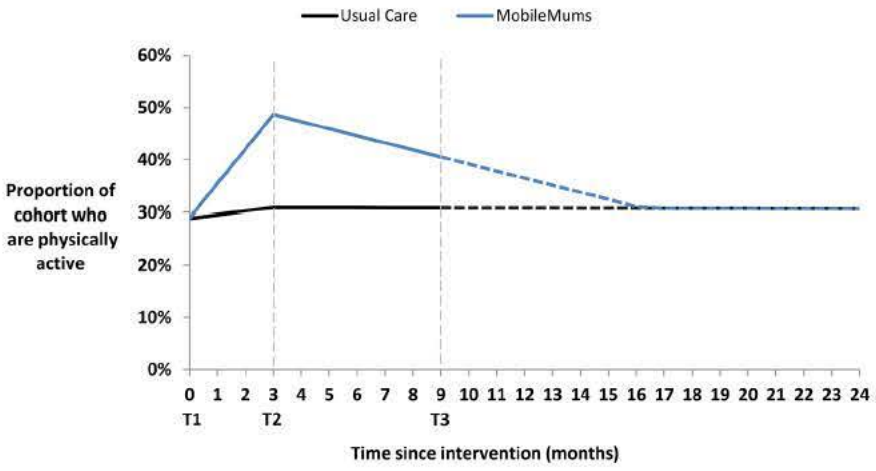


Figure 2 The expected (mean) effect of *MobileMums* on activity levels.

month. As *MobileMums* reduces the average number of months spent in the inactive state, the cost of delivering the intervention is partly offset by an expected reduction in these healthcare costs. As a result, the total expected incremental cost to the health system from introducing *MobileMums* is 1 124 209 million AUD, or 31 AUD per person.

With an expected (mean) incremental cost of 1 124 209 million AUD and an incremental improvement in health outcomes of 130 QALYs, the cost-effectiveness ratio for *MobileMums* is approximately 8608 AUD per QALY. At a cost-effectiveness threshold of 64 000 AUD, the intervention can therefore be expected to be cost-effective.

Uncertainty

The pairs of incremental costs and consequences produced by the Monte Carlo simulation are shown in figure 3. *MobileMums* has a 98% probability of being cost-effective at a threshold of 64 000 AUD (98% of simulations are below the sloped threshold line). The intervention has around a 19% probability of being cost-saving and health-improving (19% of simulations are in the south-east quadrant).

The results from the scenario analyses are presented in table 3. None of the changes in assumptions had any substantial effect on the probability that *MobileMums* is cost-effective at a threshold of 64 000 AUD, which remained over 95% under all scenarios. Changes in the assumption surrounding the maintenance of changes in activity levels into the future did, however, have a substantial effect on the probability that *MobileMums* is cost-saving. If changes were entirely mitigated after 9 months (T3) then the intervention would only have a 1% chance of being cost-saving, while if the observed difference in activity levels at T3 was maintained for up to 24 months *MobileMums* would have a 39% probability of being cost-saving.

Table 2 Estimated costs of delivering *MobileMums* in Queensland, Australia, in 2014 AUD

	Total cost (AUD)	Cost per participant (AUD)
Development of the computer programme for sending automated text-messages	14 204	0.39
Sending text-messages	620 999	17.08
Providing additional programme materials	621 388	17.08
Behavioural counsellors (24 required)		
Salaries	438 628	12.06
Equipment	36 231	0.99
Travel costs	388 368	10.68
Programme coordinators (5 required)		
Salaries	122 248	3.36
Office costs	35 885	0.98
Total	2 277 950	62.64

AUD, Australian dollar.

DISCUSSION

Principal findings

The results from this study suggest the *MobileMums* intervention would be a cost-effective use of health resources in Queensland, Australia. While the expected health benefits of the intervention are modest, with an average health improvement of only 0.0036 additional QALYs, the cost of the intervention, after taking into account reduced healthcare utilisation, is low at just 31 AUD per person. Consequently, the expected cost-effectiveness ratio is 8608 AUD per QALY, which is far below the estimated willingness to pay for an additional QALY in Australia of 64 000 AUD.[5] Neither parameter nor modelling uncertainty have a substantial effect on this conclusion.

Study strengths and limitations

This study has been largely informed by the results of a recent 9-month randomised controlled trial. By using a decision-analytic model, it was possible to extrapolate these findings to consider the costs and consequences of

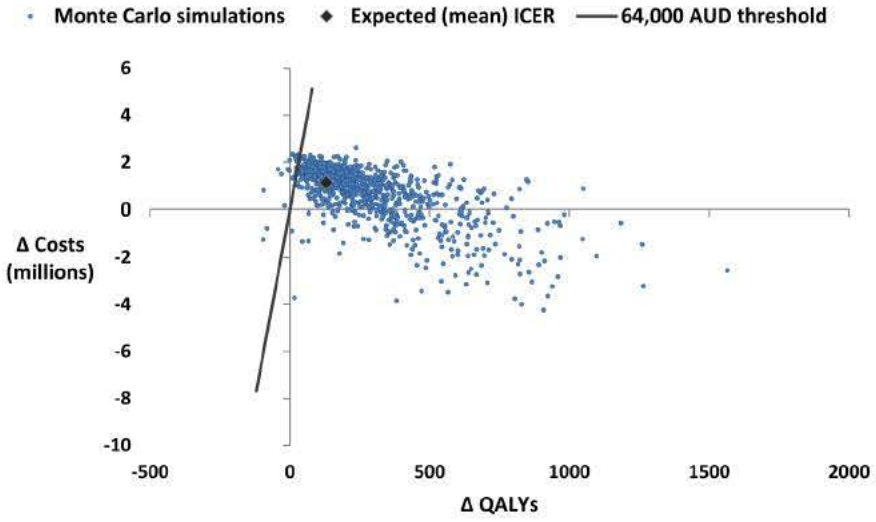


Figure 3 Cost-effectiveness plane for *MobileMums* versus usual care with 1000 sets of incremental costs and effects randomly drawn from the 10 000 Monte Carlo simulations along with the expected (mean) incremental costs and effects and a cost-effectiveness threshold of 64 000 AUD. AUD, Australian dollars; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

MobileMums if it were offered in practice to a large cohort of women and to account for expected costs and consequences beyond the trial's time horizon. Although several assumptions underpin this approach, they were subjected to sensitivity analyses which have shown them to have little effect on the overall conclusion that the intervention is likely cost-effective.

With the effect of *MobileMums* on activity levels expected to last for less than 2 years, and under the conservative assumption that only longer-term changes in activity will affect the risk of an individual developing future chronic health conditions, the model used is only required to have a short-time horizon. However, if *MobileMums* does prompt some long-term improvements in physical activity then the benefits of the intervention will be understated. In addition, while the simplicity of the model used has advantages, particularly for ease of exposition, there are limitations. In particular, only those changes in activity enough to move participants between the two states of the model are captured, with any changes of activity levels within a state overlooked.

Comparison with other studies

While a number of economic evaluations of physical activity interventions have been undertaken, there is significant methodological heterogeneity making direct comparisons difficult in many cases. Of those studies which use a similar methodology, that is, using a

Table 3 Results from the scenario analyses which examine whether the intervention remains cost-effective for a range of assumptions

	Mean change (95% credible interval) caused by *MobileMums*			Probability *MobileMums* is	
Scenario	Total costs (AUD)	QALYs	Expected (mean) ICER	Cost-effective (%)*	Cost-saving (%)
Base case	1 124 209 (1 102 044 to 1 146 374)	131 (126 to 135)	8608	98	19
Changes in activity levels entirely mitigated at 9 months (T3)	1 363 736 (1 363 736 to 1 372 716	103 (102 to 105)	13 186	97	1
Changes in activity levels maintained from 9 months to 24 months	240 173 (217 066 to 263 281)	232 (227 to 236)	1037	97	39
Number of counsellors and coordinators required increased by 50%	1 456 518 (1 434 365 to 1 478 670)	131 (126 to 135)	11 152	98	15
Number of counsellors and coordinators required reduced by 50%	823 527 (802 374 to 844 680)	130 (127 to 134)	6306	98	24
Cohort size increased by 50% to 54 546 women	1 643 613 (1 610 282 to 1 676 943)	196 (190 to 202)	8390	98	20
Cohort size reduced by 50% to 18 182	585 020 (574 005 to 596 035)	65 (63 to 67)	8959	98	17

*At a threshold of 64 000 AUD.
AUD, Australian dollars; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

decision-analytic model as a framework for analysis with the cost per quality-adjusted (or disability-adjusted) life-year estimated, many of the interventions are found to be cost-effective. For example, the 'green prescription' programme in New Zealand is found to have an incremental cost of 3000 AUD per QALY,[27] while Cobiac *et al*[28] found a pedometer intervention in Australia to be cost-saving and an internet-based intervention to have an incremental cost of 4000 AUD per QALY. However, the cost-effectiveness of such physical activity intervention is by no means guaranteed. Cobiac *et al*[28] find that a referral to exercise scheme has an incremental cost of 100 000 AUD per QALY, while a 8-week social support programme was found by Roux *et al*[29] to have an incremental cost of 95 000 AUD per QALY.

Interestingly, while these other studies typically assumed that the benefit from physical activity interventions was only through reducing the incidence of future chronic diseases, this study demonstrates that they are also likely to produce an immediate improvement in health-related quality-of-life. Active participants in the trial of *MobileMums* reported higher health-related quality-of-life than those who were physically inactive, so that *MobileMums* is expected to be cost-effective even without any long-term changes in activity levels. With this immediate improvement in quality-of-life missed in most analyses of physical activity interventions, these studies may well have underestimated the full benefits from effective physical activity interventions.

Policy implications

Health prevention programmes in Queensland, and across Australia, have recently been going through a period of disinvestment. However, if the goal of the health system is to maximise health outcomes then there seems little reason for prevention health interventions to be treated any differently to a curative intervention. While the *MobileMums* intervention can only be expected to provide a modest improvement in health-related quality of life for the average participant, it does provide a meaningful improvement in terms of population health. Healthcare resources should be directed to those uses which provide best value for money, that is, the greatest improvement in health outcomes for a given level of cost. Given the relatively low cost of delivering *MobileMums*, the intervention can be expected to provide good value for money and is likely a cost-effective use of healthcare resources given the estimated willingness-to-pay for an additional QALY in Australia.

Providing the intervention across Australia can be expected to provide a similar level of value for money. Levels of physical inactivity are similar across Australia[3] and costs, such as those associated with the counsellors and coordinators, should also be comparable. While differences in costs make it more difficult to generalise our results to other countries, the results of this study are still likely to be of relevance in many high-income countries with similarly high levels of physical inactivity. It would seem likely that a programme such as *MobileMums* would provide good value for money if provided in such countries. However, this is an area where further research is required.

CONCLUSION

MobileMums can be expected to be a cost-effective use of health resources in Queensland, Australia. If the objective of Queensland Health is to maximise population health outcomes given a finite budget, then *MobileMums* should be freely provided.

Twitter Follow Adrian Barnett at @aidybarnett

Acknowledgements Computational resources and services used in this work were provided by the High Performance Computer and Research Support Unit, Queensland, University of Technology, Brisbane, Australia.

Contributors ALM, YDM, BSF, AGB and NG conceived and designed the experiments. ALM, YDM, AGB, BSF and NG performed the experiments. EB, AGB and NG analysed the data. EB, ALM, YDM, AGB and NG wrote the paper.

Funding This study was supported by a National Health and Medical Research Council project grant number 614244.

Competing interests None declared.

Ethics approval The trial used to inform this analysis was registered retrospectively with the Australian Clinical Trials Registry (ACTRN12611000481976). Ethical clearance was obtained through the Queensland University of Technology Human Research Ethics Committee (Application number 0900001407).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The full data set is available by emailing the first author of the study.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

REFERENCES

1. World Health Organization (WHO). *Global health risks: mortality and burden of disease attributable to selected major risks*. Geneva: World Health Organization (WHO), 2009.
2. Lee I, Shiroma E, Lobelo F, *et al*. Impact of physical inactivity on the world's major non communicable diseases. *Lancet* 2012;380:219 29.
3. Australian Bureau of Statistics. *Australian health survey: first results, 2011 2012*. Canberra: Australian Bureau of Statistics, 2012.
4. Begg S, Vos T, Barker B, *et al*. *The burden of disease and injury in Australia 2003*. Canberra: Australian Institute of Health and Welfare, 2007.
5. Cadilhac D, Magnus A, Cumming T, *et al*. *The health and economic benefits of reducing disease risk factors*. Victoria: VicHealth, 2009.
6. Australian Institute of Health and Welfare. *Key indicators of progress for chronic disease and associated determinants*. Canberra: Australian Institute of Health and Welfare, 2011.
7. Love E, Rose M, Verhoef M. Women's social roles and their exercise participation. *Women Health* 1992;19:15 29.
8. Brown W, Mishra G, Lee C, *et al*. Leisure time physical activity in Australian women: relationship with well being and symptoms. *Res Q Exerc Sport* 2000;71:206 16.
9. Brown W, Trost S. Life transitions and changing physical activity patterns in young women. *AM J Prev Med* 2003:25:140 3.
10. Nomaguchi K, Bianchi S. Exercise time: gender differences in the effects of marriage, parenthood, and employment. *J Marriage Fam* 2004;66:413 30.

11. Fjeldsoe BS, Miller YD, O'Brien JL, *et al*. Iterative development of MobileMums: a physical activity intervention for women with young children. *Int J Behav Nutr Phys Act* 2012;9:151.
12. Biggs A. *Health in Australia: a quick guide*. Canberra: Parliament of Australia, Department of Parliamentary Services, 2013.
13. Sculpher MJ, Pang FS, Manca A, *et al*. Generalisability in economic evaluation studies in healthcare: a review and case studies. *Health Technol Assess* 2004;8:iii iv, 1 192.
14. Li R, Zeki L, Hilder L, *et al*. *Australia's mothers and babies*. Canberra: Australian Institute of Health and Welfare, 2010.
15. Marshall A, Miller Y, Graves B, *et al*. Moving MobileMums forward: protocol for a larger randomized controlled trial of an improved physical activity program for women with young children. *BMC Public Health* 2013;13.
16. Fjeldsoe B, Miller Y, Graves N, *et al*. Randomized controlled trial of an improved version of MobileMums, an intervention for increasing physical activity in women with young children. *Ann Behav Med* 2015. in press.
17. Gray A, Rivero Arias O, Clarke P. Estimating the association between SF 12 responses and EQ 5D utility values by response mapping. *Med Decis Making* 2006;26:18 29.
18. Medical Services Advisory Committee. *Technical guidelines for preparing assessment reports for the Medical Services Advisory Committee*. Canberra: Medical Services Advisory Committee, 2012.
19. Pharmaceutical Benefits Advisory Committee. *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee*. Canberra: Pharmaceutical Benefits Advisory Committee, 2013.
20. Claxton K, Walker S, Palmer S, *et al*. *Appropriate perspectives for health care decisions*. York: Centre for Health Economics, University of York, 2010.
21. Queensland Health. *Health practioners' (Queensland Health) certified agreement. HPEB2*, Queensland Health, 2011.
22. Australian Government Department of Health and Ageing. *Medicare benefits schedulebook: operating from 01 July 2011*. Canberra: Department of Health and Ageing, 2011.
23. Australian Institute of Health and Welfare (AIHW). *Australian hospital statistics 2011 12. Health services series no. 50*. Canberra: AIHW, 2013.
24. Drummond M, McGuire A. *Economic evaluation in health care: merging theory with practice*. New York: Oxford University Press, 2001.
25. Shiroiwa T, Sung Y K, Fukuda T, *et al*. International survey on willingness to pay (WTP) for one additional QALY gained: what is the threshold of cost effectiveness? *Health Econ* 2009;19:422 37.
26. Briggs A, Sculpher M, Claxton K. *Decision modelling for health economic evaluation*. New York: Oxford University Press, 2006.
27. Dalziel K, Segal L, Elley R. Cost utility of physical activity in counselling. *Aust NZ J Public Health* 2005;30:57 63.
28. Cobiac L, Vos T, Barendregt JJ. Cost effectiveness of interventions to promote physical activity: a modelling study. *PLoS Med* 2009;6.
29. Roux L, Pratt M, Tengs TO, *et al*. Cost Effectiveness of Community Based Physical Activity Interventions. *Am J Prev Med* 2008;35 (6):578 88.

INTERNATIONAL JOURNAL OF BEHAVIORAL NUTRITION AND PHYSICAL ACTIVITY

RESEARCH Open Access

Iterative development of MobileMums: a physical activity intervention for women with young children

Brianna S Fjeldsoe[1†], Yvette D Miller[2†], Jasmine L O'Brien[3†] and Alison L Marshall[3*†]

Abstract

Background: To describe the iterative development process and final version of 'MobileMums': a physical activity intervention for women with young children (<5 years) delivered primarily via mobile telephone (mHealth) short messaging service (SMS).

Methods: MobileMums development followed the five steps outlined in the mHealth development and evaluation framework: 1) conceptualization (critique of literature and theory); 2) formative research (focus groups, n= 48); 3) pre testing (qualitative pilot of intervention components, n= 12); 4) pilot testing (pilot RCT, n= 88); and, 5) qualitative evaluation of the refined intervention (n= 6).

Results: Key findings identified throughout the development process that shaped the MobileMums program were the need for: behaviour change techniques to be grounded in Social Cognitive Theory; tailored SMS content; two way SMS interaction; rapport between SMS sender and recipient; an automated software platform to generate and send SMS; and, flexibility in location of a face to face delivered component.

Conclusions: The final version of MobileMums is flexible and adaptive to individual participant's physical activity goals, expectations and environment. MobileMums is being evaluated in a community based randomised controlled efficacy trial (ACTRN12611000481976).

Keywords: Mobile phone, Exercise, Postnatal, mHealth, Text messaging, SMS

Background

Evidence-based advancements in health behaviour change research require thorough and transparent reporting of intervention development and content. Recent literature has called for: 1) interventions to be developed based on behaviour change theory, published evidence and formative research [1,2]; and, 2) publication of the intervention development process, including details of the final program content using standardised descriptors and language [3-5]. To date, few authors have reported on their intervention development methods, and published evaluations rarely provide the level of detail required to replicate the intervention. However, there are notable examples of authors who have provided this level of detail in publications e.g., [6-8]. These gaps in the literature limit our ability to advance health behaviour change practice and policy [2].

There are published frameworks that guide the process of developing health behaviour change interventions, such as: Intervention Mapping [9], and the Medical Research Council's Framework for developing and evaluating complex interventions to improve health [10]. More recently, three frameworks have been specifically created to guide the development of mHealth interventions (interventions primarily delivered via mobile telephone technology): the Multiphase Optimisation Strategy (MOST) [11]; the Sequential Multiple Assignment Randomized Trial (SMART) [11]; and, the mHealth Development and Evaluation framework [12]. A common theme among these frameworks is the integration of information sources to inform intervention design, including published evidence, theory and formative research

* Correspondence: alison.marshall@qut.edu.au
†Equal contributors
[3]School of Public Health, Institute of Health and Biomedical Innovation, Queensland University of Technology, Kelvin Grove, Queensland, Australia
Full list of author information is available at the end of the article

BioMed Central

© 2012 Fjeldsoe et al.; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

with the target group. The MOST and SMART frameworks involve multiple phases of randomised trials of separate intervention components to determine the best combination. However, the MOST framework violates the common assumption of many behaviour change theories: that theoretical constructs (such as outcome expectancies, self-regulation etc.) are interconnected and posited to influence behaviour when targeted in concert, not in isolation. Furthermore, the resources and time required to recruit participants and test intervention components in multiple, sufficiently-powered experimental trials can be prohibitive. The SMART framework is also specific to time-varying adaptive interventions (where intervention content is adapted over time depending on participant behaviour change progress), which was never the intention of the intervention described in this paper. The mHealth framework is an iterative process of refining complete mobile phone interventions based on concurrent and sequential quantitative and qualitative research among the target group. This framework maintains a strong focus on dissemination throughout the development process. For these reasons, we have used the mHealth framework to describe the development of our intervention.

The aim of this paper is to describe the iterative development process and final version of a physical activity intervention designed specifically for women with young children (<5 years). The intervention, called 'MobileMums', is a 12-week program delivered primarily via mobile telephone short messaging service (SMS). After describing the development process using the mHealth framework, we will describe the intervention components necessary to adequately replicate the MobileMums intervention [4] using the language defined in the taxonomy of behaviour change techniques [3] to demonstrate how the intervention content was guided by Social Cognitive Theory [13,14].

Methods and results

The development of MobileMums followed the five steps of the mHealth framework [12]: 1) conceptualisation; 2) formative research; 3) pre testing; 4) pilot testing; and, 5) qualitative research for intervention refinement. In our application of the framework, Steps 1 and 2 were conducted concurrently; after which three iterations of the MobileMums program were tested sequentially through Steps 3 to 5 (Figure 1). The findings of each step were used to refine the MobileMums program before subjecting it to the next step in the development and evaluation framework: consequently this paper describes the methods and results of each step sequentially.

Step 1 conceptualisation

MobileMums was conceptualised following a review of existing evidence and theories of behaviour change. Epidemiological evidence clearly identified women with young children as a priority group for physical activity intervention. Women with young children are consistently shown to be less active than women of the same age without children [15,16] or women with older children [15,17,18]. The child-rearing stage of life has also been identified as a time when behaviours and routines are naturally changing [19] and when women's behaviour can influence that of her immediate family [19].

The review of intervention literature revealed that most physical activity interventions targeting women with young children used community-based pram walking groups [20-23]. Overall, the evidence that this intervention approach assisted women to increase their physical activity was equivocal and most studies reported poor group attendance rates. Greater behaviour change success was observed following theory-based face-to-face (F2F) counselling interventions. However, this intervention approach was resource intensive, and also

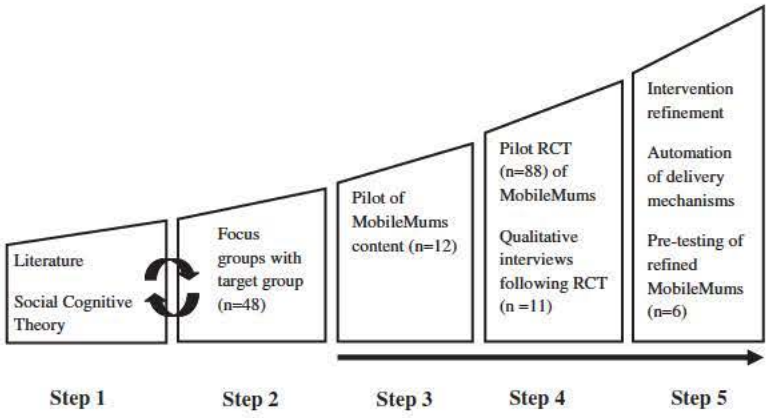


Figure 1 Methods used to inform the development of MobileMums based on the five step mHealth Development and Evaluation framework.

suffered low participant adherence [24-28]. Collectively, the evidence indicated that women with young children would benefit most from theory-based, personalised interventions that offer flexible delivery mechanisms to increase adherence.

Social Cognitive Theory [13,14] has been widely used in physical activity intervention research. Constructs from this theory have been endorsed as important for eliciting initiation of physical activity behaviour change in the general adult population [29] and specifically among women with young children [25,30]. The underlying principle of this theory is reciprocal determinism: the way an individual's cognitions, environmental perceptions and behaviour interact and influence each other [13,14]. The balance of influences emphasised in this theory were congruent with the theoretical constructs (i.e., social support, self efficacy) found to elicit behaviour change in the two mediator analyses previously conducted on physical activity interventions among women with young children [25,30]. This evidence led to the apriori selection of Social Cognitive Theory as the theoretical foundation of MobileMums in favour of other possible health behaviour theories (e.g. Theory of Planned Behaviour).

Step 2 formative research

In order to refine the scope of the intervention content and regimen [12], we conducted focus groups with women with young children to explore their perceptions of and needs for physical activity interventions. Women were recruited via posters and flyers displayed in general practice clinics, Playgroup locations, the public hospital antenatal clinic, and the public library of a community located in Queensland, Australia. To be eligible to participate, women had to have at least one child aged less than 5 years, and be able to speak and understand English. Consistent with standard methods for conducting qualitative research [31], recruitment continued until no new information was collected from each new focus group. A moderator guide was used to standardise discussion topics across groups. Each group was audio recorded and transcribed verbatim. Transcripts were analysed by two independent researchers (BF and AM) and moderated by a third researcher (YM). All analysts were experienced in conducting qualitative research. The thematic analysis followed a systematic and iterative process, whereby major themes and categories were identified and used to classify data from each group, then across the complete dataset [31]. A University Human Research Ethics Committee approved the study.

Forty-eight women with young children (aged between 16 and 45 years) participated in one of eight focus groups. Most participants (41/48) were married and a third (16/48) were pregnant at the time of participating. One third of participants (16/48) had a weekly household income less than AUD $600 per week and one quarter (13/48) had a Year 10 equivalent level education.

Nearly all participants were aware of the Australian physical activity recommendations [32] for duration (i.e., 30-minutes per day), but were less informed about the recommended frequency (i.e., most days of the week). Most participants understood moderate-intensity activities were sufficient for health benefit. Walking and water-based activities were the most common activities identified as being health-enhancing. Participants most commonly reported a desire to do more walking, swimming and gym classes. The availability of free, convenient, trustworthy childcare was revealed as the primary perceived need for women to increase their physical activity. Other perceived facilitators for physical activity included opportunities to avoid heat via indoor activities and opportunities for access to group activities, such as mothers walking groups, to assist with motivation.

> *"....the best bit* [about the walking groups] *was just getting to talk to other mums week after week. You developed friendships, and they encouraged you to come back the next week and always had something useful to share".*

Some participants raised potential barriers to attending organised group sessions such as allocated times not suiting their weekly schedules or their child's disposition on the day, finding trustworthy childcare and proximity of a group location to their home. Women most preferred to receive informal advice about physical activity from acquaintances (e.g., partner, female friends) that were currently active or had a history of being active.

When discussing flexible modes of receiving support for physical activity, participants in each group raised the use of mobile telephones. On further probing by the moderator it was found that all participants owned a mobile telephone, carried them all the time and primarily used them for SMS. Outgoing calls were limited to 'emergencies' due to high call costs and clarity of service. Participants liked the idea of receiving personalised health-related messages via SMS. SMS were preferred over calls because messages could be read or responded to at a time that was personally convenient.

> *"it's [SMS] not like a phone call. . .you are probably doing something like bathing a kid or actually busy or something and you've got to get to the phone. With a message you can always get to it later"*

Following the findings of the focus groups, we systematically reviewed the available evidence on use of SMS to deliver behaviour change interventions [33]. From this

review, we concluded that MobileMums would need to: deliver tailored SMS content to individuals; establish rapport between the SMS recipient and sender; and, encourage two-way SMS communication. Since this review was published in 2009 another five reviews of SMS-delivered behaviour change interventions have been published and corroborate the findings of our earlier review [34-38].

Step 3 Pre testing

In this development phase the feasibility and acceptability of the proposed SMS content, structure and frequency was tested in a qualitative study design. Participants were recruited through a local Playgroup and were eligible if they had a child aged under 5 years, owned a mobile telephone, were currently not meeting physical activity guidelines, and had intentions to increase their physical activity in the next 30 days. Participants provided written, informed consent and then participated in a F2F interview to collect details relevant for tailoring SMS content (i.e., their name, child's name and physical activity preferences). During the two week test period participants were sent five MobileMums SMS per week at random times during the day between 8 am and 6 pm. SMS were generated using manual tailoring processes and sent using an off-the-shelf software package from a local telecommunication provider. This package used Microsoft Outlook as the user interface and did not allow for bulk sending of SMS to participants nor automated processing of incoming SMS from participants. After two weeks, a semi-structured F2F feedback interview was conducted, which included questions about preferred SMS frequency, timing, language and content. To explore language-to-text translations, participants were asked to convert a verbalised physical activity message to an SMS they would send to a friend. Participants were then asked to show the interviewer their phone so that the SMS could be recorded from the screen. The feedback interviews were audio recorded, transcribed verbatim and thematically analysed. A University Human Research Ethics Committee approved the study design.

Twelve participants aged from 17 to 39 years participated in the pre-testing. All women who consented to participate completed the pre-testing. One quarter (3/12) of participants had a weekly household income below AUD $600 and for one quarter (3/12) Year 10 was their highest level of education.

SMS frequency and timing

Participants recalled receiving between 4 and 11 SMS over the two week period (10 were sent), and most found the SMS frequency was acceptable. One participant noted that although the SMS were *"probably a little bit excessive, it was still good because it doesn't hurt to get a text"*. Another participant who reported the SMS to be too frequent explained that she only thought this when a *"SMS was sent late afternoon one day followed by early in the morning the next day"* (i.e., based on the break between receiving SMS rather than the frequency).

Treatment of SMS

Participants reported reading all of the SMS sent to them. One participant indicated that occasionally she did not read the SMS straight away but waited until a time that suited her. Most participants stored the SMS after reading them and discussed storing SMS so they could refer to the details at a later stage (particularly SMS with details of local physical activity opportunities).

SMS language

All participants reported the SMS were easy to read and understand. When participants were instructed to write an SMS to a friend, the resulting SMS language and content varied (see Table 1). Participants used conversational language and tone, and used very little punctuation in the SMS they wrote. Participants also used a wide range of abbreviations, but common words across participants were always abbreviated such as: you = u; to = 2; for = 4; today = 2 day; and, Tuesday = tues. These common abbreviations were used hereafter in MobileMums SMS (see Table 1).

Table 1 Examples of participant's language-to-text translation when instructed to type a SMS to a friend about a MobileMums-related topic

Verbal instructions to write SMS	Exact SMS that participant typed on her phone
• Get your friend to come to a walking group with you. The walking group is at Apex Park on Tuesday at 9 am. Let them know there is childcare too.	• Walking group @ Apex 9 am tues childcare for free
	• Do you want 2 join a walking group at apex park on tues at 9 am
	• Hey darl can u cum ta walking thing on Tues at 9 starts at apex
• Tell your friend that exercise can help her lose weight and reduce her stress levels.	• Hi Julie, exercise helps you lose weight and reduce stress. Wendy
	• Jen u cn lose fat n stress less if u exercs
	• Kerry if u exerc u dont get fat and stress
• Get your friend to ask her partner to look after the kids so you can go for a walk together.	• Hi Jill, ask Greg to look after the kids so we can go for a walk. Sally
	• Go 4 walk 2 day? get gav 2 look after kids
	• Hey I was wondering if use arnt doing anything would brad mind the kids while we go for a walk and catch up.

SMS Content

Most participants thought the SMS content was acceptable, suggesting no changes. One participant suggested that it would be good to let the mums know that other mums were receiving these messages and would be attending the local physical activity opportunities that were promoted. Most participants stated that the SMS content was not new to them but that it prompted them to exercise. SMS that presented unknown information to participants included those that: promoted new opportunities for exercise in the local area; informed of the relationship between exercise and breastfeeding; and, reminded them that incidental or household activity can be classified as exercise, if completed at appropriate intensity and durations. Participants liked the SMS that taught them new things, but also liked being reminded about content they already knew. It was also noted that women used the term 'exercise' (rather than 'physical activity') when discussing the content of the SMS and typing SMS to their friend. Our previous qualitative research has shown that women with young children perceive the term 'exercise' to represent moderate-to-vigorous intensity physical activity [39], which is what MobileMums aimed to promote.

The key findings from this development step, which informed the next iteration of MobileMums, were that: the maximum proposed frequency of 5 SMS/week was acceptable; the SMS language was acceptable; some abbreviations (e.g., u, 2, 4) were commonly used; the term 'exercise' should be used in MobileMums content; SMS that include details of promoted local exercise opportunities were likely to be stored by women for later reference; and, some women may want to connect with other mums who were also receiving the program.

Step 4 pilot RCT

In line with the goals of Step 4 [12], the first complete version of MobileMums was evaluated in a pilot randomised controlled trial (RCT) compared to a minimal contact control group [40]. This first iteration of MobileMums was initiated with an individual, F2F counselling session with a trained behavioural counsellor in a community facility. The aim of this F2F session was to build rapport and a sense of accountability with the MobileMums counsellor, establish behavioural skills (e.g., goal setting, self monitoring), and collect information in order to tailor the SMS. Participants received tailored SMS for 12 weeks (frequency 2–4 SMS/week). In addition to these SMS, participants also received a weekly goal check SMS that asked them to reply and indicate whether they had reached their exercise goal or not (i.e., participants received a maximum of 5 SMS/week). Based on the participant's reply to this goal check SMS, they received a tailored SMS response. Participant's also received a telephone follow-up call with the behavioural counsellor six weeks into the program, and support from a self-nominated MobileMums support person (who also received two tailored SMS each week). Throughout the program participants had access to: information brochures on physical activity; a A5 sized refrigerator magnet designed to facilitate goal setting and self-monitoring; and an online forum within a community-based website to assist women to connect with one another.

Eighty-eight women (mean age 30 years ±SD 6 years) participated in the pilot RCT, which involved outcome assessments at baseline, 6-weeks (mid-intervention) and 13-weeks (end of intervention). For a detailed description on this intervention evaluation see Fjeldsoe, Miller, & Marshall (2010). Briefly, the results showed that MobileMums produced short-term increases in the frequency of self-reported moderate-to-vigorous intensity physical activity, in the range of 1.32-1.82 days/week [40]. We also found that short-term (baseline to 6-weeks) changes in goal setting skills and self efficacy significantly mediated the short-term impact of MobileMums on moderate-to-vigorous intensity physical activity [41]. Process evaluation with 34 women who received the MobileMums program indicated that the women regularly replied to weekly goal check SMS and frequently used the refrigerator magnet (about two thirds (22/34) were using the magnet daily post intervention). Almost all (33/34) of the intervention participants reported reading all of the MobileMums SMS they received. However, the on-line MobileMums discussion forum was not used at all.

Half of the intervention participants (17/34) rated MobileMums as 'extremely useful' or 'useful' and a further 14 participants rated it as 'somewhat useful' in supporting their exercise goals [40]. The behavioural counsellor noted that a major barrier to intervention engagement for participants was the location of the initial F2F session in a community facility.

Post-intervention interviews conducted with 11 women confirmed that program satisfaction was high [40]. Participants particularly liked: that MobileMums focused on their needs (and not their children's needs); getting information about local exercise opportunities (although they wanted more details on costs, childcare etc.); the refrigerator magnet; and the weekly goal check SMS. These women thought that their self-nominated MobileMums support person was not useful and attributed this to competing demands for the support person's time and attention (i.e., full-time employment).

Outcomes from the pilot RCT and follow-up interviews that informed further refinement of the MobileMums program included: 1) women needed greater flexibility regarding the location of the initial F2F consultation with the behavioural counsellor (i.e., their home rather

than a location determined by the counsellor); 2) the role of the support person required clearer definition to ensure women selected the most appropriate person in their life and the support person SMS needed to more directive; 3) the on-line discussion forum was not used so another option for women to connect with one another should be identified; and, 4) access to additional information (beyond that offered in the SMS) regarding the promoted local exercise opportunities was desirable.

Step 5 qualitative research for intervention refinement

Prior to developing the next iteration of MobileMums, we convened a steering group of health professionals and service delivery agents who were interested in widespread dissemination of a physical activity intervention for women with young children (i.e., maternal health nurses from the public hospital, child health nurses from community organisations, local government health promotion officers). The steering group reviewed the findings from the pilot RCT and advised that two key facilitators for the dissemination of MobileMums into practice would be: 1) an automated software program to generate and send SMS and manage incoming SMS replies from participants, to minimise the need for personnel time, and 2) a formalised handbook to guide the systematic delivery of the F2F consultation, since in practice the program would be delivered by multiple staff (not a single behavioural counsellor as in our pilot study).

After attracting additional research funding we were able to engage a professional software developer to produce a MobileMums-specific web-based application to send and receive SMS. This application allows administrators (i.e., MobileMums behavioural counsellors) to enter participant data into a web-based interface, which is then stored in a secure database (supported by *mySQL*). The program then merges these participant fields with pre-developed frameworks to generate personalised SMS and sends the SMS according to the predetermined schedule (i.e., frequency and days/week). Each SMS is sent within a three-hour window (between 6 am and 7 pm) based on the participant's preference. Most importantly, the software uses algorithms to automatically reply with a tailored, behaviourally-appropriate response to the participant's replies to the weekly goal check SMS (yes/no reply requested). If participant's goal check SMS response does not match the predicted reply words (i.e., less than 5 characters and starting with "y" or "n"), the administrator is notified via email so that the SMS can be read and an appropriate SMS response triggered. Based on findings in Step 4, we also created a dedicated MobileMums website that included detailed physical activity information, a discussion forum with improved usability (e.g., thread tracking) and a searchable exercise directory of local opportunities.

We created a comprehensive MobileMums Training Guide to guide the content of the initial F2F and 6-week counselling sessions and train behavioural counsellors. This book contains reviews of the benefits of exercise in the postnatal period, and the theoretical underpinnings of MobileMums. It also contains information on effective counselling techniques to support behaviour change. Finally, the training guide describes a 10-step process to guide the initial F2F counselling session and a 6-step process to guide the 6-week follow-up telephone counselling call. We also created another book, the MobileMums Participant's Handbook, to outline the steps in each of the counselling sessions and provide participants with space to record decisions made during their behavioural counselling sessions.

Six women with young children were recruited from the sample of participants who had been involved in the MobileMums pilot RCT (described in Step 4) to test the initial F2F consultation with the behavioural counsellor (at a preferred location) and program initiation procedures for support person registration. Women were also asked to visit the new MobileMums website (specifically the discussion forum and on-line exercise directory) and to provide written feedback on these web-based components via a mailed questionnaire. Four of the six women received the first two weeks of the automated MobileMums SMS: this allowed us to test the software's functionality in terms of automated responses to participant's goal check replies. Following this, the women completed a semi-structured telephone interview to give feedback on the F2F consultation, SMS content, program materials (e.g., on-line exercise directory), and support person registration process.

The feedback interviews provided further ideas for refining the program. These were: the need to include more affordable exercise opportunities in the on-line exercise directory, in particular walking routes; a desire to have a description of the exercise directory entries from the perspective of a woman who had engaged in the activity; and, a preference for a Facebook© group over the MobileMums discussion forum. Through the software function testing we identified the need to screen participant replies if more than four characters were included in the reply (i.e., more than a "yes" or "no" response was given). This refinement was necessary since some participants provided extra information if for example, they didn't meet their goal (e.g., *No, but only because I was sick*). In these instances the automated reply sometimes seemed insensitive or irrelevant and undermined the developing virtual relationship. Further to this we developed a protocol to guide when it was ethically important to personalise the SMS reply. This included if the

participant goal check reply referred to: personal or child health issues; domestic violence; relationship difficulties; depression, grief, or crisis management; financial difficulties; as well as other issues directly related to their MobileMums participation. This protocol was added to the MobileMums Training Guide.

A final round of user testing was conducted with three women and their support people. The complete 12-week SMS program was administered to identify potential bugs within the web-based application and automatic response mechanisms. This round of user testing identified possible risk of habituation to receiving the MobileMums SMS at exactly the same time each day (e.g., precisely 9:00 am). Therefore, the program was modified to ensure each SMS was sent at a randomly selected time within the three hour window. Also, the women commented that the SMS they received in response to their goal check replies were too immediate (within seconds), revealing the automated nature of the program and posing a threat to the earlier-identified need for rapport between the SMS recipient and sender (see Step 2). In response to this, the web-based application was modified so that the goal check replies are sent between 5- and 60-minutes after the participant response was received.

Final version of the MobileMums intervention

This section describes the MobileMums program as it currently stands being evaluated within a community-based RCT. Each component of the MobileMums intervention is described separately and in more detail below. As an overview, the 12-week intervention is initiated with a semi-structured F2F consultation with a trained behavioural counsellor, after which participants receive five tailored SMS/week during Weeks 1 to 4 and four SMS/week during Weeks 5 to 12. During Week 6 participants receive a follow-up telephone counselling call (TC) from their behavioural counsellor. Throughout the intervention, participants have ongoing access to their MobileMums Participant Handbook, MobileMums website with on-line exercise directory, MobileMums Facebook© group, MobileMums refrigerator magnet, and information brochures. During the F2F consultation each participant is asked to identify a MobileMums support person. The support person also receives tailored SMS encouraging them to offer instrumental, emotional, or informational support to assist the participant to be more active.

In finalising the content this version of the MobileMums intervention, we revisited how we operationalised the constructs of the Social Cognitive Theory (self efficacy, goal setting skills, outcome expectancies, social support and perceived environmental opportunity) into behaviour change techniques [3]; (see Additional file 1). Particular care was taken to ensure that within each intervention component (i.e., SMS, initial F2F consultation) there was even coverage of all five of the theoretical constructs (e.g., equal emphasis on each construct across the 52 SMS sent to each participant). In designing the intervention content, certain theoretical constructs (i.e., outcome expectancy, perceived environmental opportunity) were targeted more often in the early stages in the intervention (i.e., first 6 weeks) than later in the intervention. This differential timing of targeting constructs was based on evidence that outcome expectancies are particularly important in the early adoption phase of physical activity behaviour change [14,42] and was confirmed by the findings of Steps 3 and 4 that women wanted to know what exercise opportunities existed in their local areas to assist them to start new routines.

Initial F2F consultation: the aim of this consultation is to: establish rapport between the participant and the counsellor; to gather information in order to tailor the SMS content; and, to initiate the behaviour change process. The behavioural counsellor guides the participant through a 10-step process outlined in the MobileMums Participant Handbook, which participants can make notes in and keep. The 10-step process guides participants to: 1) establish the purpose and scope of the session; 2) review their current exercise patterns based on baseline assessment data; 3) discuss realistic outcome expectancies of regular exercise; 4) negotiate required social support for regular exercise and identify a support person; 5) identify potential cues and environmental opportunities for regular exercise; 6) set a SMART exercise goal; 7) set weekly rewards for goal attainment; 8) plan a weekly schedule for exercise; 9) identify potential barriers and feasible solutions; and, 10) evaluate their commitment to the plan. During this consultation, participants also receive state-of-the-art information brochures on exercise and a MobileMums refrigerator magnet. Participants are also informed of how to access the MobileMums Facebook© group, MobileMums website, and online exercise directory. This consultation occurs in a location chosen by the participant (e.g., their home) and lasts between 25- and 45-minutes.

Behavioural counsellor: the personnel employed to deliver the initial F2F and 6-week consultations were required to hold a health-related bachelor degree and government clearance for working around children. Counsellors underwent extensive training in the principles of promoting moderate-to-vigorous intensity physical activity, the constructs of the Social Cognitive Theory, effective counselling skills (e.g., active listening), and familiarisation with issues specific to the target group. The counsellors were provided with the MobileMums Training Guide, had multiple one-on-one training

sessions and engaged in role play prior to contact with participants.

MobileMums refrigerator magnet: the refrigerator magnet is 15 × 21 cm and includes a magnetic erasable pen (see Figure 2). The magnet has a daily planner for participants to plan and track their exercise across the week. During the F2F consultation, the behavioural counsellor guides the participant to write on their magnet their exercise goal, weekly reward, and exercise plan ('What, When, Where and with Whom' they will exercise) for the first week of the program. Participants are encouraged to update the reward and plan for each subsequent week of the program and SMS prompt participants to use the magnet regularly. The support person SMS also refer to the magnet to encourage support people to facilitate the planned sessions of exercise, to monitor participant's weekly goal progress and to assist in operationalizing rewards.

Facebook© group: participants are informed of the MobileMums Facebook© group (a private page), which they could request entry to via sending a friend request to the MobileMums coordinator. The coordinator posted an initial comment on the 'wall' of the Facebook© group, which welcomes women and encourages them to introduce themselves to other mums in the group. Communications on the Facebook© page are monitored weekly by the coordinator for incorrect or offensive information, but is otherwise not interfered with. Women can also send private one-to-one messages to other women in the group.

MobileMums website and on-line exercise directory: the website contains information on evidence supporting the benefits of postnatal exercise, a link to the Facebook© group, and photos and testimonials of previous MobileMums. The website also includes the exercise directory, which allows participants access to a searchable directory of opportunities to exercise in their local area. These opportunities are categorised by type (i.e., Walking Routes, Parks, Group Classes, Gyms, Personal Training, Swimming & Aqua Aerobics) and are searchable by map. Each entry in the directory includes details such as: location, contact details, facilities available (including on-site childcare), associated costs, potential risks, and a description written by the MobileMums behavioural counsellor who reviewed the activity. Participants also receive a hard-copy of the directory specific to their local neighbourhood during the initial F2F consultation.

MobileMums SMS: the SMS content is tailored to the women's exercise goal, their rewards and expected outcomes for reaching their goal and the neighbourhood that they live in (see Additional file 1 for example SMS). In addition, the SMS wording is tailored based on the: participant's name and gender; support person's name and gender; youngest child's name; and name of participant's behavioural counsellor. Women receive five SMS per week for four weeks (1 goal check SMS and 4 others) and four SMS per week for the remaining eight weeks (1 goal check SMS and 3 others). The goal check SMS is sent every Monday and asks participants whether or not they met their weekly exercise goal. If the participant replies to the goal check SMS then they receive a tailored SMS in reply (i.e., an additional SMS to the 4 or 5 per week). This goal check reply is tailored to whether the participant reached their goal or not (e.g., *Jenny, its*

Figure 2 MobileMums refrigerator magnet.

OK. It might take time 2 get in2 the swing of things. Think about what went wrong & find at least 1 way 2 make it easier this wk. Jacqui -MobileMums).

MobileMums support person SMS: during the initial F2F consultation each participant is guided to identify the tasks that would be supportive to them reaching their exercise goal and then identify the most appropriate person in their lives to fulfil these tasks (e.g., partner, family member, friend, or neighbour). Participants are then given a letter inviting their identified person to be their MobileMums support person for the duration of the 12-week program. The letter asks the potential support person to log-in to the MobileMums website to provide consent, some personal details (i.e., exercise habits, relationship to participant) and their mobile telephone number. Once they have entered this information on-line an automated SMS is sent to them requesting that they reply to confirm their consent. Consenting support people receive three personalised SMS per week within their three hour nominated send time (e.g., 9–12 am). These SMS provide prompts and ideas to provide instrumental, emotional, or informational support to assist their participant to reach her exercise goal. Every second week one of the three SMS that the support person receives is tailored to whether the participant they support responded to their weekly goal check (e.g., *Luke, congratulate Jenny. She met her goal last wk. Can u help make time 4 her reward? Its a bubble bath. Jacqui- MobileMums*).

6-week telephone consultation: during Week 6 each participant receives a follow-up telephone consultation with their behavioural counsellor. This consultation is guided by a 6-step process outlined in the MobileMums Participant Handbook and aims to reflect on participant progress during the first six weeks and to update exercise goals, rewards and plans for the subsequent six week period. Data collected during this call are entered into the online database by the behavioural counsellor, so that SMS sent during Weeks 7 to 12 are relevant to the participant's most recent exercise goal and rewards.

Copies of any MobileMums resources are available from the last author on request.

Discussion

This paper described the process of developing the MobileMums physical activity intervention and the final version currently undergoing efficacy testing. This level of detail is rarely provided in research literature, but is essential if the field of behaviour change interventions is to advance. There are currently special interest groups collaborating with peer-reviewed journals to introduce protocols that require authors to include this level of detail in published intervention evaluations [2,43]. Currently, most journals require authors to comply with CONSORT guidelines when reporting on behavioural interventions, which includes a single check point about 'precise details of the interventions intended for each group and how and when they were actually administered' [44]. Generally however, this is covered by minimal details of what and when. If further details of where, how and why are to be included in intervention descriptions then the length and formatting restrictions of some journals will need adjusting to accommodate the additional information.

An issue experienced in the development of the MobileMums intervention which may be relevant for other mHealth interventions, is the time required to develop the program, secure funding, then systematically develop and evaluate the program. This delay in implementation and evaluation means that by the time results are published and practice is impacted, the technology has often already progressed. Step 1 of the MobileMums development process commenced in 2006. During our initial focus groups women felt that the use of smart phone applications was not feasible due to the minority of women who had access to this technology. Six years later, the high penetration of smart phones may have changed this perception. There is a growing body of published behaviour change interventions delivered via smart phone applications [45,46]. However, some of the key facilitators of the success of MobileMums have been unique features of SMS and may not transfer to applications. For example, women expressed perceived accountability to the behavioural counsellor because the two-way SMS communication maintained a 'human aspect' to the intervention. Throughout the development process the MobileMums intervention content remained grounded in Social Cognitive Theory. While it has been noted that most traditional health behaviour change theories are static in nature and may not provide adequate guidance to mHealth interventions [38], the Social Cognitive Theory served MobileMums well enough to guide the behaviour change techniques. However, in future iterations of MobileMums it may be possible to adapt the content of the SMS based on the pattern of previous weekly goal check replies (rather than just the reply to each weekly goal check) or on objectively assessed physical activity patterns detected by the mobile handset either via Bluetooth connection to a wrist-worn accelerometer [47] or via accelerometers that are now commonly incorporated into the handset [48]. These advances in technological capability may require researchers to embrace more dynamic theories and to follow more complex development processes, such as those outlined in the SMART framework [11].

Throughout the development process the MobileMums intervention has evolved to include other non

m-health delivered components (e.g., participant handbook, Facebook group), however the majority of intervention contact with participants and their support person is via SMS. As described in this paper the necessary additions of other delivery methods have been based on the findings of the comprehensive formative development process undertaken with the target group. Future research should explore how the non m-health components of the intervention could be translated to sole mHealth delivery, and how the effectiveness of the program is affected as a result.

Conclusions

The process of developing MobileMums involved many phases of formative research and pilot testing. The resultant semi-automatic program has evolved from its original manually managed iteration but has maintained strong theoretical-grounding throughout the development process. Results of a current community-based randomised controlled trial to evaluate the final version of MobileMums described in this paper will inform further translation of the intervention beyond researcher administration into community-based practice (ACTRN12611000481976).

Additional file

Additional file 1: MobileMums intervention content mapped to behaviour change techniques (Michie et al., 2011) and Social Cognitive Theory. A table displaying how each behaviour change technique (from the Michie et al., taxonomy) is targeted in the MobileMums intervention and how these relate to the theoretical basis of Social Cognitive Theory.

Abbreviations

F2F: Face to face; MOST: Multiphase Optimisation Strategy; RCT: Randomized controlled trial; SMS: Short messaging service; SMART: Sequential Multiple Assignment Randomized Trial.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

BF, YM and AM conceptualised the development of MobileMums. BF and JO collected the data used in the development of MobileMums. All authors were involved in analysing and interpreting the data. All authors read and approved the final manuscript.

Acknowledgements

We would like to acknowledge the women who participated in each step of the intervention development research and the members of the steering committee formed to guide the translation of the MobileMums from manual delivery to automated delivery. We would like to acknowledge Steve Goodwin for his contributions to software development and refinement. Some aspects of the research reported in this paper was funded by Queensland Health, while the final version of the MobileMums program was funded National Health and Medical Research Council (NHMRC) (APP #614244). AM is supported by an NHMRC Career Development Award.

Author details

[1]School of Population Health, Cancer Prevention Research Centre, The University of Queensland, Herston, Queensland, Australia. [2]School of Psychology, Queensland Centre for Mothers and Babies, The University of Queensland, St Lucia, Queensland, Australia. [3]School of Public Health, Institute of Health and Biomedical Innovation, Queensland University of Technology, Kelvin Grove, Queensland, Australia.

Received: 5 March 2012 Accepted: 4 December 2012
Published: 20 December 2012

References

1. Michie S, Abraham C: **Interventions to change health behaviours: Evidence based or evidence inspired?** *Psychol Health* 2004, **19:**29 49.
2. 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:**e126.
3. Michie S, Ashford S, Sniehotta F, Dombrowski S, Bishop A, French D: **A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO RE taxonomy.** *Psychol Health* 2011, **11:**1479 98.
4. Schulz R, Czaja S, McKay J, Ory M, Belle S: **Intervention taxonomy (ITAX): describing essential features of interventions.** *Am J Health Behav* 2010, **34:**811 821.
5. Des Jarlais DC, Lyles C, Crepaz N: **Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement.** *Am J Public Health* 2004, **94:**361 366.
6. Pfaeffli L, Maddison R, Whittaker R, Stewart R, Kerr A, Jiang Y, Kira G, Carter K, Dalleck L: **A mHealth cardiac rehabilitation exercise intervention: findings from content development studies.** *BMC Cardiovasc Disord* 2012, **12:**e36.
7. Whittaker R, Maddison R, McRobbie H, Bullen C, Denny S, Dorey E, Ellis Pegler M, van Rooyen J, Rodgers A: **A multimedia mobile phone based youth smoking cessation intervention: findings from content development and piloting studies.** *J Med Internet Res* 2008, **10:**e49.
8. Cherrington A, Martin M, Halanych J, Andreae S, Safford M, Wright M, Appel S: **Intervention Mapping as a Guide for the Development of a Diabetes Peer Support Intervention in Rural Alabama.** *Prev Chronic Dis* 2012, **9:**e36.
9. Kok G, Schaalma H, Ruiter RA, van Empelen P, Brug J: **Intervention mapping: protocol for applying health psychology theory to prevention programmes.** *J Health Psych* 2004, **9:**85 98.
10. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, Tyrer P: **Framework for design and evaluation of complex interventions to improve health.** *BMJ (Clinical Research Ed)* 2000, **321:**694 696.
11. Collins LM, Murphy SA, Strecher V: **The multiphase optimization strategy (MOST) and the sequential multiple assignment randomized trial (SMART): new methods for more potent eHealth interventions.** *Am J Prev Med* 2007, **32:**S112 118.
12. Whittaker R, Merry S, Dorey E, Maddison R: **A development and evaluation process for mHealth interventions: Examples from New Zealand.** *J Health Comm* 2012, **s17:**11 21.
13. Bandura A: *Social foundations of thought and action: A social cognitive theory*. N.J.: Prentice Hall; 1986.
14. Bandura A: **Health promotion by social cognitive means.** *Health Ed Behavior* 2004, **31:**143 164.
15. Marcus BH, Pinto BM, Simkin LR, Audrain JE, Taylor ER: **Application of theoretical models to exercise behavior among employed women.** *Am J Health Promotion* 1994, **9:**49 55.
16. Brown W, Mishra G, Lee C, Bauman A: **Leisure time physical activity in Australian women: Relationship with well being and symptoms.** *RQES* 2000, **71:**206 216.
17. Nomaguchi K, Bianchi S: **Exercise time: Gender differences in the effects of marriage, parenthood and employment.** *J Marriage Fam* 2004, **66:**413 430.
18. Brown W, Trost S: **Life transitions and changing physical activity patterns in young women.** *Am J Prev Med* 2003, **25:**140 143.
19. Falba TA, Sindelar JL: **Spousal concordance in health behavior change.** *Health Serv Res* 2008, **43:**96 116.
20. Armstrong K, Edwards H: **The effects of exercise and social support on mothers reporting depressive symptoms: A pilot randomized controlled trial.** *Int J Mental Health Nurs* 2003, **12:**130 138.
21. Currie J: **Pramwalking as postnatal exercise and support: An evaluation of the stroll Your Way to Well Being Program and supporting resources**

in terms of individual participation rates and community group formation. *Aust College Midwives* 2001, 14:21 25.
22. Watson N, Milat AJ, Thomas M, Currie J: **The feasibility and effectiveness of pram walking groups for postpartum women in western Sydney.** *Health Promotion J Aust* 2005, 16:93 99.
23. Rowley C, Dixon L, Palk R: **Promoting physical activity: walking programmes for mothers and children.** *Community Pract* 2007, 80:28 32.
24. Cody R, Lee C: **Development and evaluation of a pilot program to promote exercise among mothers of preschool children.** *Int J Behav Med* 1999, 6:13 29.
25. Miller Y, Trost S, Brown W: **Mediators of physical activity behavior change among women with young children.** *Am J Prev Med* 2002, 23:98 103.
26. Fahrenwald NL, Atwood JR, Walker SN, Johnson DR, Berg K: **A randomized pilot test of "Moms on the Move" a physical activity intervention for WIC Mothers.** *Annals Behav Med* 2004, 27:82 90.
27. Cramp A, Brawley L: **Moms in motion: a group mediated cognitive behavioural physical activity intervention.** *Int J Behav Nutr Phys Act* 2006, 3:1 9.
28. Clarke KK, Freeland Graves J, Klohe Lehman DM, Milani T, Nuss H, Laffrey S: **Promotion of physical actvity in low income mothers using pedometers.** *JADA* 2007, 107:962 967.
29. Rhodes RE, Pfaeffli LA: **Mediators of physical activity behaviour change among adult non clinical populations: a review update.** *Int J Behav Nutr Phys Act* 2010, 7:37.
30. Cramp A, Brawley L: **Sustaining self regulatory efficacy and psychological outcome expectations for postnatal exercise: effects of a group mediated cognitive behavioural intervention.** *British J Health Psych* 2009, 14:595 611.
31. Stewart D, Shamdasani P: *Focus groups: Theory and practice.* 1st edition. California, USA: Sage Publications; 1990.
32. Australian Government: *National physical activity guidelines for adults.* Canberra: Department of Health and Ageing; 2005.
33. Fjeldsoe BS, Marshall AL, Miller YD: **Behavior change interventions delivered by mobile telephone short message service.** *Am J Prev Med* 2009, 36:165 173.
34. Whittaker R, Borland R, Bullen C, Lin RB, McRobbie H, Rodgers A: **Mobile phone based interventions for smoking cessation.** *Cochrane Database Syst Rev* 2009, 4:CD006611.
35. Cole Lewis H, Kershaw T: **Text messaging as a tool for behavior change in disease prevention and management.** *Epi Reviews* 2010, 32:56 69.
36. Wei J, Hollin I, Kachnowski S: **A review of the use of mobile phone text messaging in clinical and healthy behaviour interventions.** *J Telemed Telecare* 2010, 17:41 48.
37. Krishna S, Boren SA, Balas EA: **Healthcare via cell phones: a systematic review.** *Telemed J E Health* 2009, 15:231 240.
38. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R: **Health behavior models in the age of mobile interventions: are our theories up to the task?** *Transl Behav Med* 2011, 1:53 71.
39. Collins BS, Marshall AL, Miller YD: **Physical activity in women with young children: How can we assess "anything that's not sitting"?** *Women Health* 2007, 45:95 116.
40. Fjeldsoe BS, Miller YD, Marshall AL: **MobileMums: a randomized controlled trial of an SMS based physical activity intervention.** *Annals Behav Med* 2010, 39:101 111.
41. Fjeldsoe B, Miller YD, Marshall AL: **Social cognitive mediators of the effect of the MobileMums intervention on physical activity.** *Health Psych* 2012, Advance online publication, May 21, 2012.
42. Williams DM, Anderson ES, Winett RA: **A review of the outcome expectancy construct in physical activity research.** *Annals Behav Med* 2005, 29:70 79.
43. Abrahams C: *WIDER Recommendations to Improve Reporting of the Content of Behaviour Change Interventions.* http://interventiondesign.co.uk/wp content/uploads/2009/02/wider recommendations.pdf. Last accessed 2/09/2012.
44. Altman DG, Schultz KF, Moher D, Egger M, Davidoff F, Elbourne D, Gotzsche PC, Lang T: **The revised CONSORT statement for reporting randomized trials: Explanation and elaboration.** *Annals Int Med* 2001, 134:663 694.
45. Abroms LC, Padmanabhan N, Thaweethai L, Phillips T: **iPhone apps for smoking cessation: a content analysis.** *Am J Prev Med* 2011, 40:279 285.
46. Rao A, Hou P, Golnik T, Flaherty J, Vu S: **Evolution of data management tools for managing self monitoring of blood glucose results: a survey of iPhone applications.** *J Diabetes Sci Technol* 2010, 4:949 957.
47. Hurling R, Catt M, Boni MD, Fairley BW, Hurst T, Murray P, Richardson A, Sodhi JS: **Using internet and mobile phone technology to deliver an automated physical activity program: randomized controlled trial.** *J Med Internet Res* 2007, 9:e7.
48. Xia Y, Cheung V, Garcia E, Ding H, Karunaithi M: **Development of an automated physical activity classification application for mobile phones.** *Stud Health Technol Inform* 2011, 168:188 194.

doi:10.1186/1479 5868 9 151
Cite this article as: Fjeldsoe *et al.*: Iterative development of MobileMums: a physical activity intervention for women with young children. *International Journal of Behavioral Nutrition and Physical Activity* 2012 9:151.

Submit your next manuscript to BioMed Central and take full advantage of:

- **Convenient online submission**
- **Thorough peer review**
- **No space constraints or color figure charges**
- **Immediate publication on acceptance**
- **Inclusion in PubMed, CAS, Scopus and Google Scholar**
- **Research which is freely available for redistribution**

Submit your manuscript at
www.biomedcentral.com/submit

BioMed Central

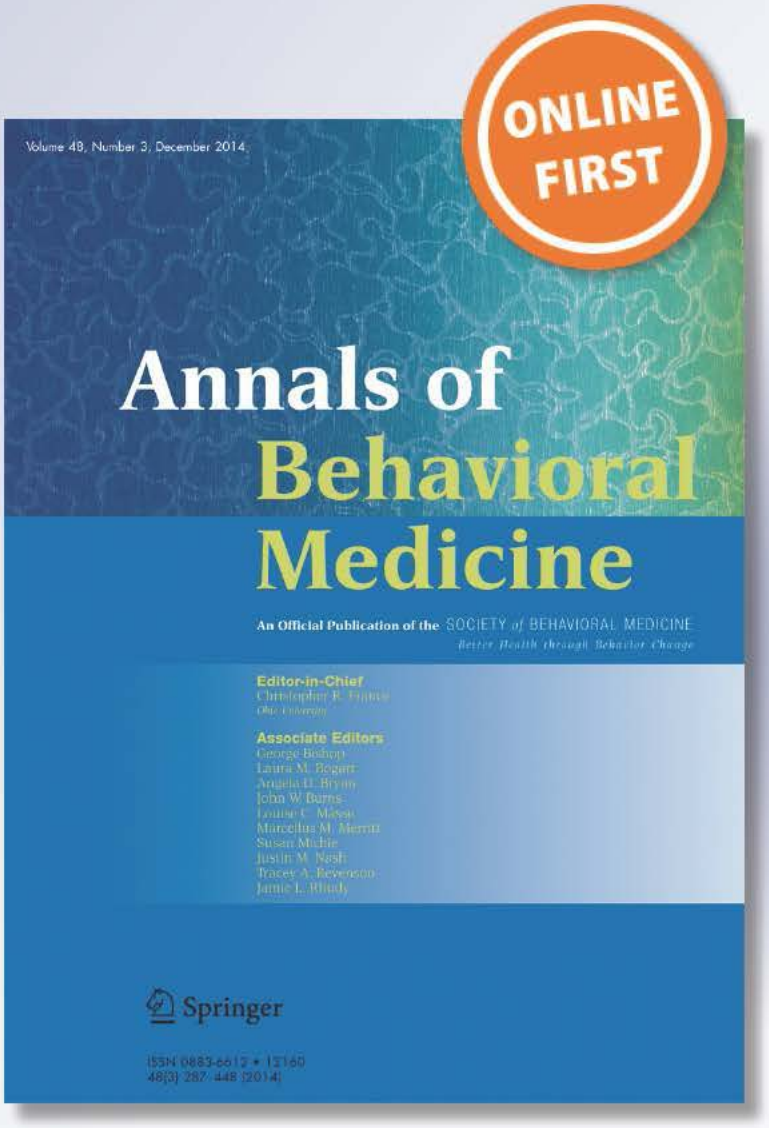
Randomized Controlled Trial of an Improved Version of MobileMums, an Intervention for Increasing Physical Activity in Women with Young Children

Brianna S. Fjeldsoe, Yvette D. Miller, Nicholas Graves, Adrian G. Barnett & Alison L. Marshall

Annals of Behavioral Medicine

ISSN 0883 6612

ann. behav. med.
DOI 10.1007/s12160 014 9675 y



Springer

Your article is protected by copyright and all rights are held exclusively by The Society of Behavioral Medicine. This e-offprint is for personal use only and shall not be self-archived in electronic repositories. If you wish to self-archive your article, please use the accepted manuscript version for posting on your own website. You may further deposit the accepted manuscript version in any repository, provided it is only made publicly available 12 months after official publication or later and provided acknowledgement is given to the original source of publication and a link is inserted to the published article on Springer's website. The link must be accompanied by the following text: "The final publication is available at link.springer.com".

Author's personal copy

ann. behav. med.
DOI 10.1007/s12160 014 9675 y

ORIGINAL ARTICLE

Randomized Controlled Trial of an Improved Version of MobileMums, an Intervention for Increasing Physical Activity in Women with Young Children

Brianna S. Fjeldsoe, PhD · Yvette D. Miller, PhD · Nicholas Graves, PhD · Adrian G. Barnett, PhD · Alison L. Marshall, PhD

© The Society of Behavioral Medicine 2014

Abstract
Background Women with young children (<5 years) are an important group for physical activity intervention.
Purpose The objective of the study was to evaluate the feasibility, acceptability, and efficacy of MobileMums—a physical activity intervention for women with young children.
Methods Women were randomized to MobileMums (n=133) or a control group (n=130). MobileMums was delivered primarily via individually tailored text messages. Moderate to vigorous physical activity (MVPA) was measured by self-report and an accelerometer at baseline, end of the intervention (13 weeks), and 6 months later (9 months). Changes were analyzed using repeated-measures models.
Results MobileMums was feasible to deliver and acceptable to women. Self-reported MVPA duration (minutes/week) and frequency (days/week) increased significantly post-intervention (13-week intervention effect 48.5 min/week, 95 % credible interval (CI) [13.4, 82.9] and 1.6 days/week, 95 % CI [0.6, 2.6]). Intervention effects were not maintained 6 months later. No effects were observed in accelerometer-derived MVPA.
Conclusions MobileMums increased women's self-reported MVPA immediately post-intervention. Future investigations need to target sustained physical activity improvements (ACTRN12611000481976).

B. S. Fjeldsoe
School of Population Health, Cancer Prevention Research Centre, The University of Queensland, Brisbane, Australia

Y. D. Miller · N. Graves · A. G. Barnett · A. L. Marshall (✉)
Institute of Health and Biomedical Innovation, School of Public Health and Social Work, Faculty of Health, Queensland University of Technology, Brisbane, Australia
e mail: alison.marshall@qut.edu.au

Y. D. Miller
School of Psychology, The University of Queensland, Brisbane, Australia

Published online: 13 January 2015

Keywords Text messaging · SMS · Mobile telephone · Exercise · Intervention · Post-natal

Introduction

Women with children aged less than 5 years are an important target for physical activity promotion. They are less active than women the same age without children [1–4] and women with older children [2, 5–7]. In addition to health benefits of physical activity experienced in the general population [8], active women with young children are less likely to develop post-natal depression [9] and retain less excess body weight following pregnancy [10, 11].

A recent systematic review of seven physical activity interventions in healthy, inactive women with young children concluded that interventions can increase the frequency of physical activity immediately post-intervention [12]. Most interventions were delivered by face-to-face contact in either group [13–17] or individual sessions [18, 19], and although generally effective at increasing physical activity, results from these trials suggest that the need for regular face-to-face contact may reduce program attendance [15, 20–22]. Overall, this review concluded that the methodological quality of research to date was poor, citing that many studies had a high risk of bias, high dropout rates, poor measurement approaches, and inadequate handling of missing data [12].

Broad-reach interventions may be suitable for this population group. Interventions that use telephone counseling and/or e-mail contact [23–25] or other mediated (non-face-to-face) intervention delivery modes may be particularly suitable for women with young children. These modes can ameliorate issues of access and reach: extending across geographic areas, reducing the burden of accessing programs in structured face-to-face settings, and reducing the cost of program delivery [26].

Author's personal copy

MobileMums is a mediated intervention that was developed through an iterative process that used theory and findings from several sources of evidence [27]. It is a 12-week physical activity program based on social cognitive theory that is primarily delivered via personalized, individually tailored mobile telephone text messages sent to participants and their nominated MobileMums social support person. The program is initiated by a face-to-face counseling session during which physical activity goals are set and data for personalizing the text messages are collected. Physical activity goals are monitored via text message throughout the intervention period and are revisited during a telephone counseling call conducted mid-intervention (6 weeks). A pilot randomized controlled trial (RCT) showed that MobileMums produced statistically significant short-term increases in the frequency (days per week) of self-reported moderate- to vigorous-intensity physical activity (MVPA) and walking for exercise mid-intervention (6 weeks; M=1.32 days/week, *standard error* (SE)=0.17 and M=1.65 days/week, SE=0.27, respectively) and immediately post-intervention (13 weeks; M=1.82 days/week, SE=0.18 and M=1.08 days/week, SE=0.24 respectively) [28]. Unfortunately, the pilot study was not adequately powered for examining intervention effects on time spent being physically active each week (duration), did not include objective measurement of physical activity, and did not assess maintenance of the intervention effect after contact finished. Pilot study participants (n=88) engaged well with the program and were satisfied that it supported them to increase their physical activity [28]. The positive feasibility and preliminary physical activity outcomes observed in the pilot study showed that the MobileMums intervention deserved further attention and evaluation in an adequately powered RCT.

The aim of this study was to evaluate whether an improved version of MobileMums was feasible to deliver, acceptable to participants, and effective at increasing MVPA in women with young children at the end of the intervention (13 weeks) and 6 months after the end of the intervention (9 months), compared with a minimal contact control group.

Methods

Formative research and iterative development processes for creating the MobileMums intervention [27] and detailed methods of the current trial are provided elsewhere [29]. This trial adhered to the CONSORT guidelines for reporting RCTs [30] and was registered with the Australian Clinical Trials Registry (ACTRN12611000481976). Ethical clearance was obtained through the Queensland University of Technology Human Research Ethics Committee (Application no 0,900,001,407).

Study Design

This was a 9-month, two-arm community-based RCT. Participants were randomly allocated to either the MobileMums intervention group or a minimal contact control group. Data were collected before the program (baseline), immediately post-intervention (time 2, 13 weeks post-baseline), and after a 6-month no-intervention maintenance period (time 3, 9 months post-baseline).

Participant Eligibility and Recruitment

Women with young children were recruited from within a 30-km radius of the Caboolture central business district (a community 45 km north of Brisbane, Australia) via one of three methods. Our primary method was from an existing database of women with young children who had participated in community surveys about infant and maternal health outcomes in 2006 and consented to being recontacted about future research. Each woman was mailed an invitation to participate, followed by a personalized text message (i.e., referred to them by first name) and telephone call to determine their interest and eligibility. Women were able to opt out from receiving the follow-up telephone call by replying to the text message.

Two methods of supplementary recruitment were used: (1) Clients of the Caboolture Early Years Centre were sent an invitation via the centre's Facebook group. This message was not personally tailored but provided details of the study and asked women to contact research staff via telephone or e-mail. (2) The Queensland Centre for Mothers & Babies mailed an invitation to participate in this research to their database of women with young children. These women had participated in a survey about their experience of maternity care in 2010 [31] and had consented to be contacted for further research. Only those women who contacted the MobileMums research staff via telephone, e-mail, or business reply letter were screened for eligibility.

To be eligible, women had at least one child aged between 6 weeks (most physiological and morphological changes associated with pregnancy have normalized by 6 weeks [32]) and 5 years, owned a mobile telephone, were not pregnant at the time of consent (participants remained eligible if they fell pregnant during the 9-month trial), lived within the designated residential area and planned to remain there for the next 12 months, and were able to read and understand English. Any woman who had been advised not to exercise by her doctor was asked to receive her doctor's clearance before participating. Once eligibility was established, women provided informed verbal consent over the telephone, and their baseline physical activity assessment was scheduled.

Author's personal copy

Data Collection

Specific details of the data collection procedure were provided in the MobileMums protocol paper [29] and summarized here. Data at all three assessment points were collected via self-administered questionnaire, telephone interview, and objective activity monitors (accelerometers). Participants were sent an assessment package that contained as follows: an introductory letter, an accelerometer, an accelerometer logbook, a self-administered questionnaire, an instruction/reference sheet for use during the telephone interview, and a business reply mailbag. Participants received courtesy calls from trained research assistants on days 3 and 7 after the package was sent to ensure its receipt and correct use of the accelerometer. Where possible, the scripted telephone-interview-administered questionnaires were conducted by the trained research assistants during one of these courtesy calls. Research assistants were blind to participants' group allocation at baseline but may not have remained blind to group allocation at times 2 and 3 due to participants disclosing information about their treatment during their interview. All participants received a nominal gratuity (A$20 gift voucher) for each completed assessment to recognize their contribution to the research.

Feasibility and Acceptability Outcomes

Intervention implementation data were assessed via the self-report questionnaire (i.e., recall and treatment of text messages and use of supplementary intervention materials) or objective tracking of delivery data (i.e., duration of initial and 6-week counseling session, number of text messages sent, number of goal check text message responses received, and number of unprompted [extraordinary] text messages sent by participants). Participants' perceived usefulness of the program was assessed in the self-report questionnaire on a five-point Likert scale ranging from 1 (*poor*) to 5 (*excellent*).

Efficacy Outcomes

Change in MVPA was assessed via telephone interviews using a validated physical activity survey to assess specific types of MVPA done for specific purposes (e.g., brisk walking for exercise) and an objective accelerometer.

Telephone Interview

The Australian Women's Activity Survey that was developed to specifically assess physical activity among women with young children [33] was administered during the telephone interview. The survey assesses women's typical weekly activity in the past month across five domains (planned, transport, childcare, domestic, and work related) and three intensity levels (light, moderate, and vigorous). Interview-administered survey data have good test-retest reliability (ICC=.80, 95 % confidence interval (CI) [0.65, 0.89]) and acceptable criterion validity (compared to accelerometer data; correlation=.28, p=.01) [33]. The key variables extracted from the survey were duration (minutes per week) and frequency (days per week) in the planned and transport domains for MVPA (including brisk walking and moderate- and vigorous-intensity activities) and brisk walking only. To be categorized as meeting the Australian physical activity guidelines [34], participant's survey data had to indicate at least 150 min and at least 5 days per week of MVPA.

Accelerometer

Total accumulated MVPA was assessed using data from a waist-worn ActiGraph GT1M accelerometer (ActiGraph, LLC, Fort Walton Beach, Florida). Participants were asked to wear the accelerometer for all waking hours (minimum 10 h/day) for seven consecutive days, removing it only for sleep or water-based activities. They were asked to record each time that they put the accelerometer on or took it off, including any non-wear activities (e.g., water-based activities) in a logbook. The accelerometer was set to record data in 1-min epochs, thus providing output as counts per minute (cpm). Bouts of ≥60 min of zero cpm (allowing for <3 min of counts 1 to 49 cpm) were excluded as non-wear time [35]. Invalid days (days with <10-h wear or excessive counts ≥20,000 cpm) were discarded. Standardized cut-points [36] were applied to delineate moderate-intensity activity (574 to 4944 cpm) and vigorous-intensity activity (≥4945 cpm). These accelerometer cut-points were chosen as they were created using research which collected accelerometer data during a broad set of field-based activities (e.g., yard work, housework, family care, occupation, recreational walking, and conditioning), which are more like the types of activities undertaken by women with young children, than is walking or running on a treadmill in a laboratory. Importantly, walking with and without a stroller has been shown to be a moderate-intensity activity, when assessed using a portable gas analyzer to measure oxygen uptake [37]. The chosen cut-points are more likely to accurately capture this type of activity as moderate. Data are reported as averages for valid days (minimum one valid day) on a per week scale. The average per day was scaled to weeks to make these data more comparable with the self-reported physical activity outcomes (minutes per week). The "minutes per week" (duration) variable derived from the accelerometer data considered moderate- to vigorous-intensity minutes that were accumulated in bouts of at least 10 min (allowing for a maximum of two 1-min epochs below the threshold within every 10-min bout). Treating accelerometer data this way is consistent with the updated American College of Sports Medicine and American

Author's personal copy

Heart Association physical activity recommendations for adults [38] and the methods used by Troiano et al. [39] to treat accelerometer-derived physical activity data. The "bouts per week" (frequency) variable indicated the number of bouts that the participant accumulated at least 10 min of MVPA (allowing for a maximum of two 1-min epochs below the threshold within every 10-min bout). To be categorized as meeting the Australian physical activity guidelines [34], participant's accelerometer data had to indicate at least 150 min/week and at least five bouts per week, based on the variable definitions described above.

Sample Size

Sample size was based on the clinically meaningful increase in physical activity observed in our pilot study at mid-intervention (40 min/week) [28]. Using the standard deviation of 102 min/week (from survey data), and assuming 80 % power and two-sided significance of 5 %, we needed 102 women per group. Anticipating a 25 % dropout, this figure was inflated to 128 per group (256 in total).

Randomization

Participants were randomized to either the intervention or control group in three strata according to their baseline physical activity frequency. Physical activity frequency was determined using data from a single item asking participants to indicate (on a scale from 0 to 7 days) how many days per week they "exercised for at least 30-min" in the past 12 weeks. This single item has acceptable validity against ActiGraph accelerometers for assessing frequency (days per week) of at least 30-min sessions of MVPA in women with young children (correlation=.38, $p<.001$; unpublished data). Each participant was classified as either not at all active (exercised 0 days per week), somewhat active (exercised between 1 and 4 days per week) or sufficiently active (exercised 5 days or more per week) [40]. Randomization was managed by the project coordinator using three lists created by the fourth author using the "sample" function in the R software package to create random permuted blocks of size 10 with a 1:1 allocation ratio. While the primary focus of this intervention was to increase women's physical activity, it was also designed to support ongoing participation by widening participants support network for physical activity. For this reason, we chose to not exclude women who were considered active during our screening process. Women who were habitually physically active and did not foresee any benefit of participating opted out of the study during the informed consent process (see Fig. 1).

MobileMums Intervention

MobileMums was created using the five step mHealth Development and Evaluation process. Relevant literature, theory, and quantitative and qualitative evidence from formative research with the target group were reviewed [27]. Each component of the MobileMums intervention operationalizes at least one construct of social cognitive theory (self-efficacy, goal-setting skills, outcome expectancies, social support, and perceived environmental opportunity) into a behavior change technique [27]. This is elucidated using the taxonomy of behavior change in our earlier publication [27].

The MobileMums intervention was initiated by a face-to-face counseling session with a trained MobileMums behavioral counselor, after which participants received 12 weeks of individually tailored theory-based text messages and a follow-up telephone counseling session with their behavioral counselor at 6 weeks. Participants also received supplementary resources: a MobileMums Participant Handbook, a MobileMums goal-tracking refrigerator magnet, and standard physical activity information brochures, as well as details for joining a dedicated MobileMums Facebook group and a MobileMums website with a searchable online exercise directory. Each participant was also guided to identify a MobileMums support person who also received 12 weeks of individually tailored, theory-based text messages. Access to these resources can be provided upon request to the corresponding author.

Face to Face Counseling Session

The aim of the face-to-face counseling session was to establish rapport between the participant and their MobileMums counselor, work through the standardized stepwise MobileMums Participant Handbook, collect information to personalize and tailor the text message content, and initiate the behavior change process. Using the MobileMums Participant Handbook as a guide, participants were asked to reflect on their physical activity patterns (using a one-page feedback summary from baseline accelerometer-measured physical activity assessment), identify expected outcomes of being active, set a specific, measurable, achievable, realistic, timelined (SMART) physical activity goal and identify a personal reward for reaching their goal, identify barriers to reaching their goal and strategies to overcome them, and identify the support that they required for reaching their goal, including a specific person to be their MobileMums support person. At the end of the counseling session, participants rated their confidence to reach their goal on a ten-point scale ranging from 1 (*not at all confident*) to 10 (*extremely confident*). If a participant rated their confidence four or below, their goals and/or strategies were adjusted until they felt more confident that they could reach their goal. This session occurred at a time and location identified by the participant (e.g., usually their home).

Author's personal copy

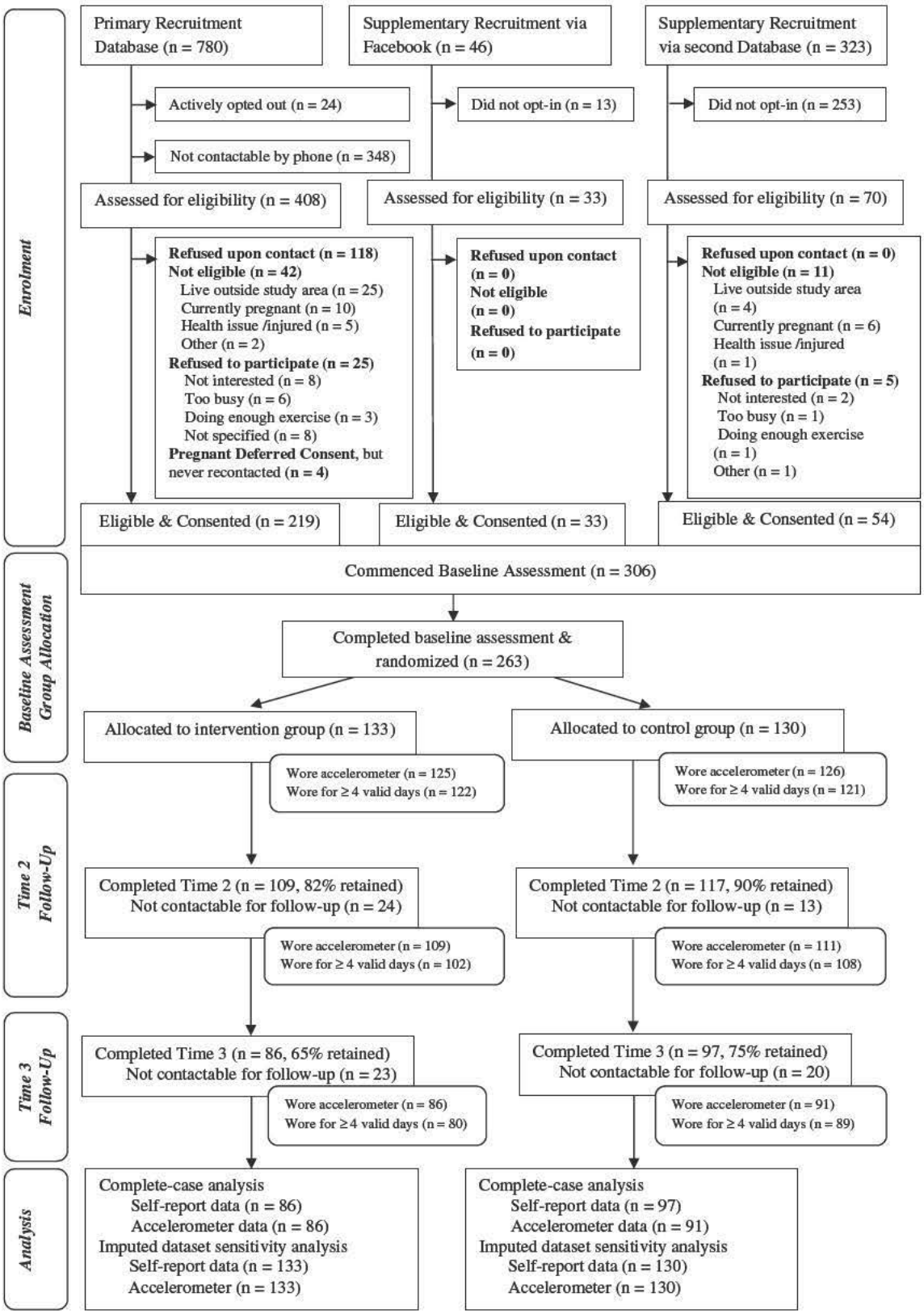


Fig. 1 Participant recruitment and retention flowchart

Variation in intervention delivery was minimized by only having two tertiary educated MobileMums counselors who worked very closely and debriefed with each other and the study coordinator weekly. Counselors were required to hold

Author's personal copy

government clearance for working around children. Each counselor underwent intensive training in the evidence for why promoting MVPA was beneficial, the constructs of the social cognitive theory, effective counseling skills (e.g., active listening), and familiarization with issues specific to the target group. Counselors were provided with the MobileMums Training Guide, had multiple one-on-one training sessions, and engaged in role play training prior to contact with participants. Both counselors audio-recorded three sessions (selected at random) with permission from the participant: These recordings did not undergo fidelity analysis but were reviewed by the first author to provide counselors with feedback on their performance.

MobileMums Text Messages

Over the 12-week program, participants were sent 52 individually tailored text messages via a customized, automated web-based program. Each text was tailored by linking the automated program with a secure participant database created using data collected by the counselors during the face-to-face counseling session. The content was tailored to each participant's name, counselor's name, goal, neighborhood, preferred reward, and/or expected outcomes for reaching her goal. Where appropriate, text messages were also personalized using the participant's youngest child's name and their support person's name and gender.

During weeks 1 to 4, participants were sent five text messages per week and four text messages per week thereafter. Weekly messages included one goal check message sent each Monday asking the participant to respond (e.g., "Jenny did u do all ur planned exercise last wk.? Check ur planner magnet & text me back yes or no. Jacqui—MobileMums"). If the participant replied to the goal check message, the program used algorithms to construct an appropriate, tailored reply. Therefore, each participant could receive an additional 11 texts if they responded to each goal check message (total text messages possible=63).

Support Person Text Messages

Support people were sent three personalized theory-based text messages per week encouraging them to offer instrumental, emotional, or informational support to their MobileMum. Four of these messages were tailored to how their MobileMum participant responded to her weekly goal check (e.g., "Luke, congratulate Jenny. She met her goal last wk. Can u help make time 4 her reward? It's a bubble bath. Jacqui—MobileMums").

Week 6 Telephone Counseling Session

During week 6, participants received a telephone call from their MobileMums counselor, and they worked through the last section of the MobileMums Participant Handbook. The aim of this session was to update the participant's exercise goals and strategies in order to refine the tailoring of the text messages sent in weeks 7 to 12.

Supplementary Resources

Throughout the program, participants had ongoing access to their MobileMums goal-tracking refrigerator magnet, MobileMums Participant Handbook, MobileMums website with searchable, online exercise directory, MobileMums Facebook group (monitored by project coordinator), and information brochures. The information brochures included standard government issue education materials on "An Active Way to Better Health" and "Exercise and Wellbeing After Pregnancy," a customized brochure on walking tracks in Caboolture, and a customized printout of "mom-friendly" activities in their local neighborhood. Women also received a brief (one page) summary of their accelerometer-measured physical activity levels following each assessment. This feedback was not considered part of the intervention but was provided to increase participant compliance with repeat assessment.

Minimal Contact Control Group

Women in the minimal contact control group received the same standard physical activity information brochures as the intervention group and had access to a separate information-only website and a separate Facebook group. Neither they did receive any of the novel MobileMums-specific resources (handbook, magnet, or text messages) nor did they have any contact with the MobileMums behavioral counselor. Consistent with the intervention group and to increase participant compliance with assessment procedures and reduce study attrition, the control group participants also received the one-page feedback summary of their accelerometer-derived physical activity levels following each assessment. With the exception of the accelerometer feedback summary, the control group treatment was designed to reflect the standard minimal care that service providers could feasibly deliver without specific funding (e.g., standard print materials and information-only website and Facebook access), and provided an altruistic comparison for the novel MobileMums intervention components.

Efficacy Data Analyses

Efficacy data analyses were intention to treat [30], so all participants' data were analyzed according to their randomized group regardless of compliance with the program. Change in self-reported MVPA and brisk walking and in accelerometer-derived MVPA was analyzed using repeated-

Author's personal copy

measures models. For the continuous physical activity variables, change was modeled from baseline with group and baseline physical activity as independent variables [41].

To examine the differences between groups, the means and 95 % confidence intervals were calculated at the three data collection times along with mean changes between baseline and both time 2 and time 3. We used similar repeated-measures models for the categorical physical activity variables, but used a Poisson distribution to model the counts of brisk walking days per week from the interview data, and a binomial distribution for guideline compliance data, expressing the results as prevalence ratios [42]. We used prevalence ratios instead of odds ratios, as these can be used as multipliers (i.e., how many "times more likely" a good physical activity outcome is observed in the intervention group compared with the control).

All analyses were run assuming a Bayesian paradigm using non-informative priors; hence, results are presented using means and 95 % credible intervals [43]. We used 10,000 MCMC iterations after a burn-in of 10,000. R software package (version 3.0.0) was used to create plots and impute missing data [44] and the JAGS package (version 3.2.0) to run the Bayesian models [45].

Sensitivity Analyses

Four sensitivity analyses were completed to examine the impacts of outliers, missing data at times 2 and 3, and compliance with the intervention, on intervention effects. First, we excluded data for participants with change from baseline to either times 2 or 3 that was more than three standard deviations from the mean change. Then, for each dependent variable, we ran a complete case analysis and another analysis that imputed missing data. We used a parametric multiple imputation by randomly imputing the missing data using either an exponential or categorical distribution. We used the exponential distribution for continuous physical activity variables as these data were strongly positively skewed. We checked the adequacy of the exponential assumption using a quantile–quantile plot. We used a categorical distribution for compliance with the physical activity guidelines and the interview-derived brisk walking variable on the scale of number of days per week. For these variables, the imputation was based on the marginal probabilities of the observed values. For example, if 10 % of participants were not meeting the guidelines at times 1 and 2, then missing values for the guidelines at times 1 and 2 were randomly imputed with a 10 % probability of not meeting the guidelines. For the accelerometer data, completely missing and partially missing data were imputed. If a participant had completely missing data, then their data were imputed by randomly sampling from an exponential distribution with the mean equal to the sample average from all available responses from all participants. If a participant had partially missing data (e.g., 3 days complete out of 7), then the data for their missing days were imputed by randomly sampling from an exponential distribution with the mean equal to the sample average from their available responses. Multiple imputations with ten imputed data sets were used.

Two sensitivity analyses were used to examine if the treatment effect was stronger in those who received the core components of the MobileMums intervention. These subgroup analyses were not initially planned but were conducted to understand if specific intervention components (and use of them) impacted on the intervention effect. The first analysis examined *per protocol* effects. Per protocol receipt of the intervention was defined as receiving the initial face-to-face counseling session, nominating a MobileMums support person, receiving 51 text messages over 12 weeks (since during trial delivery, one of the 52 planned text messages failed to send), and completing the 6-week telephone counseling session. Second, a subgroup of *proactive users* was identified: Proactive users were intervention participants who met the per protocol criteria described above, plus they replied to at least 8 out of the 11 goal check text messages (sent weekly from weeks 2 to 12) and reported at least weekly use of the MobileMums refrigerator magnet at time 2. The per protocol and proactive user subsamples were compared to the control group, and changes in between-group intervention effects of 20 % of the original effect were considered meaningful.

Results

Participants

Figure 1 shows the recruitment process and how participants flowed through the trial following consent. Three hundred six participants consented, and 263 (86 %) completed the baseline assessments and were randomized. There were no meaningful differences in demographic or physical activity characteristics between those considered eligible (n=331) and those randomized (n=263; Table 1). The mean age of the trial sample (n=263) was 31.9 years (SD=9.5), mean BMI was 28.1 (SD=6.9), 21.8 % had an education level no higher than year 10 (i.e., grade 10 in secondary school), and 47.7 % reported full-time home duties. The two study groups were similar.

Overall, study retention rate of the randomized sample was 86 % at time 2 (end of intervention) and 70 % at time 3 (6 months after end of intervention; see Fig. 1). Multiple logistic regression analysis showed that being in the intervention group increased the odds of not responding at time 2 (*odds ratio* (OR)=2.49, p=.06, 95 % CI [1.01, 6.72]), while non-response at time 3 was more likely among those who reported sufficient MVPA at baseline (OR=4.59, p=.01, 95 %

Author's personal copy

Table 1 Demographic and physical activity characteristics of eligible participants invited to participate in the trial and those randomly allocated to each study group

Characteristic	Eligible sample (n=331)		Intervention group (n=133)		Control group (n=130)	
	n	M (SD)	n	M (SD)	n	M (SD)
Age (years)	330	32.4 (5.5)	133	32.1 (5.2)	130	33.1 (5.3)
BMI (kg/m^2)	*Not recorded*		124	27.4 (6.8)	124	28.9 (6.9)
Age of youngest child (months)	330	27.1 (16.1)	130	26.5 (16.8)	132	26.7 (15.4)
	n	*Mdn* (25th, 75th percentiles)	n	*Mdn* (25th, 75th percentiles)	n	*Mdn* (25th, 75th percentiles)
Days per week 30 min of exercise (single item screener)	330	1 (0,3)	132	1 (0,3)	130	1 (0,3)
	n	n (%)	n	n (%)	n	n (%)
Insufficient days per week 30 min of exercise	330	291 (88.2)	132	119 (90.2)	130	116 (89.2)
Became pregnant during trial	*Not recorded*		109	7 (6.4)	117	9 (7.7)
Only one child to be cared for while exercising	329	113 (34.3)	131	42 (32.1)	130	50 (38.5)
Marriage status no partner	*Not recorded*		132	15 (11.4)	128	16 (12.5)
Identify as Aboriginal or Torres Strait Islander	*Not recorded*		132	2 (1.5)	127	2 (1.6)
Income less than $600 weekly household income	*Not recorded*		114	10 (8.8)	110	16 (14.5)
Education year 10 highest education level	*Not recorded*		131	25 (19.1)	126	31 (24.6)
Employment status full time home duties	328	154 (47.0)	130	70 (53.8)	130	66 (50.8)

CI [1.37, 15.98]). Most participants wore the accelerometer for four or more valid days (≥10 h/day) at baseline (97 %), time 2 (95 %), and time 3 (95 %; see Fig. 1).

Feasibility and Acceptability

One hundred thirty women (98 % of those randomized to the intervention) completed the initial face-to-face counseling session, and most (85 %) opted to complete the session in their home. The mean duration of this initial session was 50 min (SD=10). At the end of the counseling session, 67 % of intervention participants rated their confidence in their ability to reach their exercise goal as eight or higher on a ten-point scale (response range=5–10). One hundred eleven women (83 %) completed the 6-week telephone counseling session, which lasted on average 14 min (SD=5).

On average, intervention participants were sent 58 (SD=8; including goal check replies) text messages over the 12-week intervention period, and their nominated support person was sent 33 (SD=5) text messages. The proportion of participants replying to the goal check text messages ranged from 86 (in week 2) to 64 % (in week 10; see Fig. 2). Consistently, a higher proportion of goal check replies indicated that participants had met their goals ("yes" replies) than those that had not met their goals ("no" replies; see Fig. 2). Five participants did not respond to any goal check message. Excluding the goal check replies, on average, participants sent 1.6 (SD=2.4) extraordinary text messages to their counselors during the intervention period, which were not responded to.

At time 2, 86 % of intervention participants recalled receiving between two and seven text messages in the previous week from MobileMums (four were sent in the final week, five if they responded to the weekly goal check). Fourteen percent reported never receiving a MobileMums text message. Forty-eight percent of intervention participants reported reading the MobileMums text messages then deleting them, 36 % reported reading them then storing them, and 4 % reported deleting them without reading them at all. Forty-three percent of intervention participants reported referring to the MobileMums Participant Handbook after receiving it during the initial counseling session, 44 % reported reading the information brochures, 46 % reported accessing the MobileMums intervention website, and 32 % reported "using" the secret Facebook group. Despite never receiving one, 11 % of control participants reported referring to the MobileMums Participant Handbook (although they may have confused this with the information package that they received), 54 % reported reading the information brochures, 14 % reported accessing the MobileMums control website, and 3 % reported "using" the Facebook group (which was different to the intervention Facebook group).

Objective data on the use of the separate MobileMums websites collected via Google Analytics showed that during the intervention period, the MobileMums intervention website

Author's personal copy

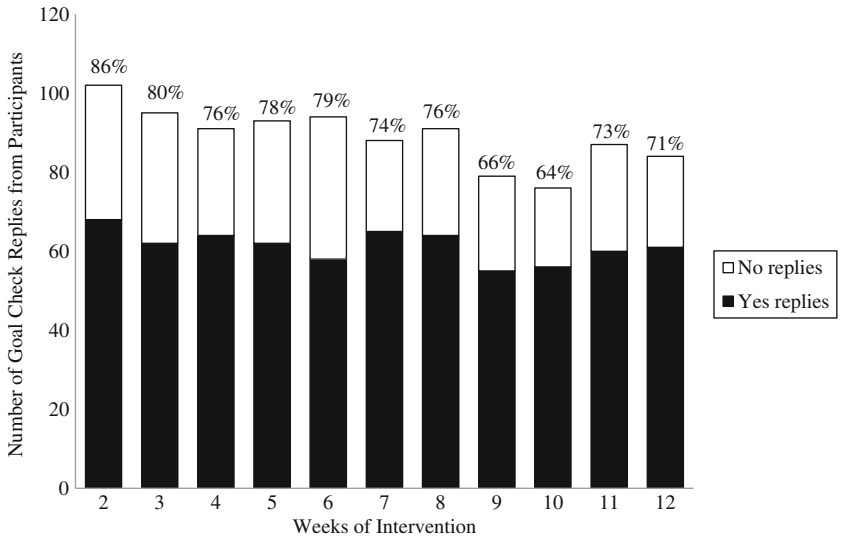


Fig. 2 Number and type of goal check replies received from participants by intervention week and the proportion of intervention participants choosing to reply each week. NB: goal checks were sent in weeks 2 12

encountered 463 sessions, of which at least 102 would have been MobileMums support people registering. There were 190 repeat sessions (41 % of the total). The average number of intervention website pages viewed per session was 3.80, and the average session duration was 3.24 min. By comparison, the control website encountered 63 sessions during the study period, of which 7 (11 %) were repeat visits. The average number of control website pages viewed per session was 3.1, and the average session duration was 1.31 min.

At time 2, 53 % of intervention participants rated the MobileMums program as "excellent" or "very good" at

Table 2 Physical activity outcomes at baseline, within group change to time 2 and time 3 for the intervention (n=133) and control (n=130) groups, and between group intervention effects

Outcome	Baseline *Mdn* (25th, 75th percentiles)	Time 2 *n*	Change to Time 2 *M* (95 % CI)	Intervention effect *M* (95 % CI)	Time 3 *n*	Change to Time 3 *M* (95 % CI)	Intervention effect *M* (95 % CI)
Self reported moderate to vigorous intensity physical activity							
Min/week							
Intervention	80.0 (0.0, 228.0)	111	72.8 [43.5, 102.1]	48.5 [13.4, 82.9]	85	54.3 [21.0, 87.2]	25.3 [12.5, 62.8]
Control	108.0 (0.0, 221.3)	119	24.3 [0 5, 50.2]		97	29.0 [0.5, 56.3]	
Days/week							
Intervention	2.0 (0.0, 6.0)	111	2.0 [1.3, 2.7]	1.6 [0.6, 2.6]	85	1.4 [0.5, 2.2]	0.4 [0.7, 1.6]
Control	3.0 (0.0, 6.0)	117	0.4 [0 3, 1.2]		97	0.9 [0.1, 1.7]	
Self reported brisk walking							
Min/week							
Intervention	20.0 (0.0, 95.0)	110	81.2 [60.3, 101.9]	33.8 [8.3, 58.9]	85	70.0 [46.5, 93.3]	13.1 [14.8, 41.6]
Control	0.0 (0.0, 90.0)	121	47.5 [29.0, 66.6]		97	57.0 [35.8, 77.2]	
Days/week							
Intervention	1.0 (0.0, 3.0)	110	2.1 [1.6, 2.6]	1.0 [0.4, 1.6]	85	1.9 [1.3, 2.4]	0.3 [0.4, 1.1]
Control	0.0 (0.0, 3.0)	121	1.1 [0.7, 1.6]		97	1.5 [1.0, 2.0]	
Accelerometer measured moderate to vigorous intensity physical activity							
Min/week							
Intervention	402.0 (218.8, 636.5)	104	8.0 [52.8, 36.4]	21.2 [25.4, 67.2]	83	54.8 [103.1, 6.2]	2.4 [46.8, 51.3]
Control	358.0 (203.9, 565.0)	107	29.2 [65.9, 8.4]		87	57.2 [97.3, 17.7]	
Bouts/week[a]							
Intervention	22.7 (14.4, 35.5)	104	1.1 [1 3, 3.6]	0.2 [3.2, 3.5]	83	1.6 [4.3, 1.2]	1.1 [4.9, 2.8]
Control	21.0 (12.0, 31.7)	107	0.9 [1.4, 3.4]		87	0.5 [3.3, 2.1]	

[a] Number of 10 min bouts of moderate to vigorous intensity activity

Author's personal copy

helping them to increase their physical activity, and a further 33 % rated it as "good."

Effects on Physical Activity

There were statistically significant between-group effects demonstrated between baseline and time 2 in favor of the intervention group (see Table 2). This included the intervention group reporting significantly more MVPA in terms of both duration (48.5 min/week) and frequency (1.6 days/week) than the control group. The intervention group also reported significantly more brisk walking duration (33.8 min/week) and frequency (1.0 days/week) relative to the control group.

There were no statistically significant between-group differences between baseline and time 3 in either duration or frequency of self-reported MVPA or brisk walking (see Table 2). There were no statistically significant between-group differences observed over time in any of the accelerometer-derived physical activity outcomes (see Table 2).

At time 2, intervention participants were, on average, 75 % more likely to report enough MVPA to meet national physical activity guidelines, compared to the control group (mean prevalence ratio 1.75, 95 % CI [1.20, 2.50]). The prevalence ratio was not statistically significant at time 3 (mean prevalence ratio 1.26, 95 % CI [0.82, 1.84]). The mean prevalence ratio of guideline compliance for accelerometer-measured weekly MVPA between the intervention and control groups was not statistically significant at time 2 (1.08, 95 % CI [0.98, 1.20]), or at time 3 (0.98, 95 % CI [0.86, 1.13]) (Table 3).

Sensitivity Analyses

Imputing missing data at time 2 or at time 3 did not alter the between-group intervention effects for self-reported or accelerometer-derived MVPA or brisk walking (data not shown). The per protocol subgroup (n=102) analyses did not alter any between-group effects or their magnitude. There were no meaningful or statistically significant differences between the control group (n=130) and proactive user subgroup (n=59) baseline characteristics (i.e., demographics and physical activity levels: data not shown). However, the proactive user subgroup analyses increased the magnitude of baseline to time 2 intervention effects for the frequency of self-reported brisk walking (from 1.0 to 1.3 days/week, 95 % CI [0.5, 2.1]).

Table 3 Physical activity guideline compliance rates at baseline, time 2, and time 3 for the intervention (n=133) and control (n=130) groups

Condition	Baseline %	Time 2 %	Time 3 %
Self reported moderate to vigorous intensity physical activity			
Intervention	29	50	42
Control	28	30	34
Accelerometer measured moderate to vigorous intensity physical activity			
Intervention	85	89	81
Control	85	82	83

Discussion

This study rigorously evaluated an improved version of the MobileMums physical activity intervention. An earlier version had previously demonstrated feasibility and efficacy for increasing women's physical activity frequency (days/week) both mid-intervention (6 weeks) and at the end of intervention (13 weeks) but was underpowered to detect statistically significant changes in physical activity duration (min/week) [27]. This version of the intervention was again shown to be feasible to deliver and received high approval from the target group. Further, it resulted in meaningful and statistically significant improvements in self-reported physical activity frequency and duration at the end of intervention (13 weeks), but this effect was not maintained at 6 months after the intervention had ceased.

The increase in self-reported MVPA duration observed immediately post-intervention in this trial (48.5 min/week) was greater than that observed in the pilot trial (18.3 min/week [28]). This difference was despite the fact that, unlike in the pilot trial, we neither excluded women who were already doing five or more days of exercise (whose capacity for change is less than those women who were considered inactive at baseline) nor did we exclude women who did not intend to increase their exercise in the next 3 months (thus only including those motivated to change). This means that the current trial included a more representative sample that was less likely to be capable of and/or ready for change. The larger effect may be explained by improvements made to MobileMums program [27]. New components added to this version of MobileMums included use of a MobileMums Participant Handbook during the counseling sessions, more thorough mapping of mom-friendly environmental opportunities for exercise which was accessible via a directory embedded in a MobileMums website, more specific selection of a MobileMums support person, and a higher dose and tailoring of support person text messages. Participants also had access to a secret MobileMums Facebook group, though use of the Facebook group was suboptimal. The use of individual intervention components that were common across the two trials were slightly better in this trial (e.g., replying to goal checks and use of the goal-tracking refrigerator magnet) [28]. An in-depth investigation of potential moderators of intervention effect, the use of each

Author's personal copy

intervention component, and changes in theoretical constructs and potential mediators may help to understand the mechanisms of change that underpinned the intervention effects observed in this trial, but are beyond the scope of this manuscript, and will be reported in a separate manuscript [29].

Evaluating the maintenance of behavior change following end-of-intervention contact is crucial to informing potential long-term effectiveness of interventions, yet few published behavior change trials include such follow-ups [26, 46]. Retention of study participants is also crucial to developing this understanding. Retention of participants in this trial was 70 % after 6 months of no-intervention contact. Despite extra attention being paid to participant retention in this trial (e.g., providing feedback on accelerometer-derived activity levels and the gratuity given to participants after each completed assessment), this retention rate is slightly below the average retention rates across a variety of physical activity intervention trials of varying length (M=78 %, range=55–97 %) [47], but similar to the average retention rate of RCTs of much shorter duration (≤13 weeks) involving post-partum women (average 74 % [12]).

Results of this trial showed that intervention group participants did not maintain the improvements observed immediately post-intervention. This may suggest that skills targeted in the intervention were not embedded into women's lives and/or were not sustained without the text message prompts. Accumulating evidence suggests that ongoing or extended intervention contact may be required to maintain accountability and prompt regular use of the learned behavioral skills for sustained positive changes in behavior to occur [48, 49]. Future iterations of MobileMums will need to identify ways to extend the intervention effect beyond the 12 weeks of intense text message contact. This may be facilitated by further, less frequent text message contact or by supplementing the intervention with ongoing contact via other mediated methods (e.g., Facebook).

Our sensitivity analyses suggest that future iterations of MobileMums should focus on increasing the proportion of women who proactively use intervention resources to maximize impact on physical activity behavior. This could be achieved through emphasizing the importance of replying to the weekly goal check text messages during the counseling sessions or by supplementing the intervention with alternative methods for enabling engagement (e.g., replying to goal checks via web or self-monitoring via a smartphone app).

Interestingly, no significant increases in physical activity frequency or duration were observed in the accelerometer-derived data. One reason we may not have been able to detect significant between group effects in the accelerometer-derived physical activity data is the possibility that all wearers were sufficiently motivated to do more activity while wearing the accelerometer, especially at baseline when the novelty of wearing the device and anticipation of feedback were at its peak (the Hawthorne effect). This may also explain why baseline activity levels appear relatively high within the accelerometer-derived data and thus limited potential to observe significant change over time in either study group.

The different patterns of behavior change observed between self-reported and accelerometer-derived physical activity data may also be explained by differences in their capacity for measuring physical activity. Since most women in the pilot study chose to set a SMART exercise goal specific to brisk walking [28], a measure that could specifically capture walking was required. The Australian Women's Activity Survey asks participants to isolate and recall specific activity domains (e.g., planned versus work related) and intensities of activity (e.g., brisk walking) with a level of detail that cannot be replicated by the accelerometer. While accelerometers are known to accurately detect MVPA, their sensitivity can neither be adjusted to individual perceptions of activity intensities nor account for load bearing while in ambulatory motion such as pushing a pram or carrying a baby nor can accelerometers specifically isolate walking from other MVPA. As accelerometers become used more frequently in intervention evaluations, further exploration of the absolute discrepancy between self-reported and accelerometer-measured physical activity changes over time may be accommodated [50].

This study was adequately powered to detect between-group differences in self-reported physical activity outcomes. The effect of the intervention was also assessed 6 months after intervention contact ceased: an estimate of intervention effect maintenance not often seen in intervention evaluation trials. Limitations of this trial include use of self-report data which are subject to recall bias, slower than expected recruitment due to the database of women initially used for recruitment being outdated (i.e., high proportion not contactable), delays in implementation of evaluation procedures at each time point due to women's busy schedules and unavailability for timely interview, research assistants may not have been blinded to participant group allocation during time 2 and 3 follow-up interviews due to participants inadvertently revealing information about their treatment during repeat telephone contacts, and insufficient power for detecting change in accelerometer-derived activity data. Nevertheless, based on the findings of this trial, the MobileMums program was successful in assisting women with young children to increase their self-reported physical activity immediately post-intervention.

This trial has advanced our understanding of the efficacy of MobileMums. The MobileMums program has been thoroughly and thoughtfully developed based on existing evidence and extensive formative work undertaken with the target group and dissemination partners. It was delivered following systematic protocols, including a standardized approach to training the MobileMums behavioral counselors and stepwise approach to conducting the face-to-face and 6-week telephone

Author's personal copy

counseling sessions. The lack of sustained intervention effects 6 months post-intervention suggests that future iterations of the program should investigate strategies that will enhance maintenance of the initial program effects. The opportunity for further developing and integrating the MobileMums program with other virtual operations is vast. For example, greater synchronicity between the text-based communications with women and the other online components, and considering whether the personalized contacts with women (the initial and 6-week counseling sessions) may be operationalized online, requires further consideration and research.

Acknowledgments We wish to thank the women of Caboolture who participated in the study. We would also like to thank project staff for their integrity and commitment, Jasmine O'Brien, Sarah Mair, Jacqueline Watts, Joy Nicols, and Kylie Heenan. Thanks also to the Queensland Centre for Mothers & Babies at The University of Queensland who assisted us by inviting women on their research database to participate in this trial. This study was supported by a National Health and Medical Research Council project grant no 614,244. The last author was supported by a National Health and Medical Research Council Career Development Award no 553,000. Computational resources and services used in this work were provided by the High Performance Computer and Research Support Unit, Queensland University of Technology, Brisbane, Australia.

Author Statement of Conflict of Interest and Adherence to Ethical Standards Authors Fjeldsoe, Miller, Barnett, Graves and Marshall declare that they have no conflict of interest. All procedures, including the informed consent process, were conducted in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

References

1. Brown W, Mishra G, Lee C, Bauman A. Leisure time physical activity in Australian women: relationship with well being and symp toms. *Res Q Exerc Sport*. 2000; 71: 206 216.
2. Adamo KB, Langlois KA, Brett KE, Colley RC. Young children and parental physical activity levels: findings from the Canadian health measures survey. *Am J Prev Med*. 2012; 43: 168 175.
3. Berge JM, Larson N, Bauer KW, Neumark Sztainer D. Are parents of young children practicing healthy nutrition and physical activity behaviors? *Pediatrics*. 2011; 127: 881 887.
4. Bellows Riecken KH, Rhodes RE. A birth of inactivity? A review of physical activity and parenthood. *Prev Med*. 2008; 46: 99 110.
5. Brown W, Trost S. Life transitions and changing physical activity patterns in young women. *Am J Prev Med*. 2003; 25: 140 143.
6. Brown WJ, Burton NW, Rowan PJ. Updating evidence on physical activity and health in women. *Am J Prev Med*. 2007; 33: 404 411.
7. Nomaguchi KM, Bianchi SM. Exercise time: gender differences in the effects of marriage, parenthood, and employment. *J Marriage Fam*. 2004; 66: 413 430.
8. Haskell WL, Blair SN, Hill JO. Physical activity: health outcomes and importance for public health policy. *Prev Med*. 2009; 49: 280 282.
9. Teychenne M, York R. Physical activity, sedentary behavior, and postnatal depressive symptoms: a review. *Am J Prev Med*. 2013; 45: 217 227.
10. van der Plight P, Willcox J, Hesketh KD, et al. Systematic review of lifestyle interventions to limit postpartum weight retention: implications for future opportunities to prevent maternal overweight and obesity following childbirth. *Obes Rev*. 2013; 14: 792 805.
11. Choi J, Fukuoka Y, Lee JH. The effects of physical activity and physical activity plus diet interventions on body weight in overweight or obese women who are pregnant or in postpartum: a systematic review and meta analysis of randomized controlled trials. *Prev Med*. 2013; 56: 351 364.
12. Gilinsky AS, Dale H, Robinson C, Hughes A, McInnes R, Lavellee D. Efficacy of physical activity interventions in post natal content coding of behaviour change techniques [published populations: sys tematic review, meta analysis and online ahead of print April 02 2014]. *Health Psychol Rev*. 2014
13. Cramp A, Brawley L. Moms in motion: a group mediated cognitive behavioural physical activity intervention. *Int J Behav Nutr Phys Act*. 2006; 3: 1 9.
14. Clarke KK, Freeland Graves J, Klohe Lehman DM, Milani TJ, Nuss HJ, Lafrey S. Promotion of physical activity in low income mothers using pedometers. *J Am Diet Assoc*. 2007; 107: 962 967.
15. Watson N, Milat AJ, Thomas M, Currie J. The feasibility and effec tiveness of pram walking groups for postpartum women in western Sydney. *Health Promot J Austr*. 2005; 16: 93 99.
16. Armstrong K, Edwards H. The effectiveness of a pram walking exercise programme in reducing depressive symptomatology for postnatal women. *Int J Nurs Pract*. 2004; 10: 177 194.
17. Monteiro SMDR, Jancey J, Dhaliwal SS, et al. Results of a random ized controlled trial to promote physical activity behaviours in mothers with young children. *Prev Med*. 2014; 59: 12 18.
18. Daley AJ, Winter H, Grimmett C, McGuinness M, McManus R, MacArthur C. Feasibility of an exercise intervention for women with postnatal depression: a pilot randomised controlled trial. *Br J Gen Prac*. 2008; 58: 178 183.
19. Fahrenwald NL, Atwood JR, Walker SN, Johnson DR, Berg K. A randomized pilot test of "Moms on the Move" a physical activity intervention for WIC Mothers. *Ann Behav Med*. 2004; 27: 82 90.
20. Armstrong K, Edwards H. The effects of exercise and social support on mothers reporting depressive symptoms: a pilot randomized con trolled trial. *Int J Ment Health Nurs*. 2003; 12: 130 138.
21. Currie J. Pramwalking as postnatal exercise and support: an evalua tion of the stroll Your Way to Well Being Program and supporting resources in terms of individual participation rates and community group formation. *Aust J Midwifery*. 2001; 14: 21 25.
22. Rowley C, Dixon L, Palk R. Promoting physical activity: walking programmes for mothers and children. *Community Pract*. 2007; 80: 28 32.
23. Albright CL, Maddock JE, Nigg CR. Increasing physical activity in postpartum multiethnic women in Hawaii: results from a pilot study. *BMC Womens Health*. 2009; 9(4).
24. Reinhardt JA, Van Der Ploeg HP, Grzegrzulka R, Timperley JG. lmplementing lifestyle change through phone based motivational interviewing in rural based women with previous gestational diabetes mellitus. *Health Promot J Austr*. 2012; 23: 5 9.
25. Lewis BA, Martinson BC, Sherwood NE, Avery MD. A pilot study evaluating a telephone based exercise intervention for preg nant and postpartum women. *J Midwifery Womens Health*. 2011; 56: 127 131.
26. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interven tions delivered by mobile telephone short message service. *Am J Prev Med*. 2009; 36: 165 173.
27. Fjeldsoe BS, Miller YD, O'Brien JL, Marshall AL. Iterative devel opment of MobileMums: a physical activity intervention for women with young children. *Int J Behav Nutr Phys Act*. 2012; 9(151)
28. Fjeldsoe BS, Miller YD, Marshall AL. MobileMums: a randomized controlled trial of an SMS based physical activity intervention. *Ann Behav Med*. 2010; 39: 101 111.

Author's personal copy

29. Marshall AL, Miller YD, Graves N, Barnett AG, Fjeldsoe BS. Moving MobileMums forward: protocol for a larger randomized controlled trial of an improved physical activity program for women with young children. *BMC Public Health.* 2013; 13(593).
30. Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA*. 1996; 276: 637 639.
31. Miller YD, Thompson R, Porter J, Armanasco A, Prosser S. *The Having a Baby in Queensland Survey, 2010*. Brisbane, Australia: The University of Queensland; 2010.
32. Artal R, O'Toole M. Guidelines of the American College of Obstetricians and Gynecologists for exercise during pregnancy and the postpartum period. *Br J Sports Med*. 2003; 37: 6 12.
33. Fjeldsoe BS, Marshall AL, Miller YD. Measurement properties of the Australian Women's Activity Survey. *Med Sci Sports Exerc*. 2009; 41: 1020 1033.
34. Department of Health and Ageing. *National physical activity guide lines for adults*. Canberra: Australian Government; 2005.
35. Winkler EA, Gardiner PA, Clark BK, Matthews CE, Owen N, Healy GN. Identifying sedentary time using automated estimates of accel erometer wear time. *Br J Sports Med*. 2012; 46: 436 442.
36. Swartz AM, Strath SJ, Bassett DR, O'Brian WL, King GA, Ainsworth BE. Estimation of energy expenditure using CSA accelerometers at hip and wrist sites. *Med Sci Sports Exerc*. 2000; 32: S450 S456.
37. Brown W, Ringuet C, Trost S, Jenkins D. Measurement of energy expenditure of daily tasks among mothers of young children. *J Sci Med Sport*. 2001; 4: 379 385.
38. Haskell W, Lee I, Pate R, et al. Physical activity and public health: Updated recommendation for adults from the American College of Sports Medicine and the American Heart Foundation. *Circulation*. 2007; 116: 1081 1093.
39. Troiano RP, Berrigan D, Dodd KW, Msse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc*. 2008; 40: 181 188.
40. Department of Health and Ageing. *National Physical Activity Guidelines for Australian Adults*. Canberra: Australian Government; 2005.
41. Barnett AG, van der Pols JC, Dobson AJ. Regression to the mean: what it is and how to deal with it. *Int J Epidemiol*. 2005; 34: 215 220.
42. Deddens JA, Petersen MR. Approaches for estimating prevalence ratios. *Occup Environ Med*. 2008; 65: 501 506.
43. Bland JM, Altman DG. Bayesians and frequentists. *BMJ*. 1998; 317: 1151 1160.
44. R Core Team. R: A language and environment for statistical comput ing. Vienna, Austria: R Foundation for Statistical Computing; 2013.
45. Plummer M. JABS Version 3.3.0 User Manual. 2012.
46. Fjeldsoe BS, Neuhaus M, Winkler E, Eakin E. Systematic review of maintenance of behavior change following physical activity and dietary interventions. *Health Psychol*. 2011; 30: 99 109.
47. Waters LA, Galichet B, Owen N, Eakin E. Who participates in physical activity intervention trials. *J Phys Act Health*. 2011; 8: 85 103.
48. Middleton KM, Patidar SM, Perri MG. The impact of extended care on the long term maintenance of weight loss: a systematic review and meta analysis. *Obes Rev*. 2012; 13: 509 517.
49. Donaldson EL, Fallows S, Morris M. A text message based weight management intervention for overweight adults. *J Hum Nutr Diet*. 2014; 27: 90 97.
50. Winkler E, Waters L, Eakin E, Fjeldsoe B, Owen N, Reeves M. Is measurement error altered by participation in a physical activity intervention? *Med Sci Sports Exerc*. 2013; 45: 1004 1011.

Provided for non-commercial research and education use.
Not for reproduction, distribution or commercial use.

This article appeared in a journal published by Elsevier. The attached copy is furnished to the author for internal non-commercial research and education use, including for instruction at the authors institution and sharing with colleagues.

Other uses, including reproduction and distribution, or selling or licensing copies, or posting to personal, institutional or third party websites are prohibited.

In most cases authors are permitted to post their version of the article (e.g. in Word or Tex form) to their personal website or institutional repository. Authors requiring further information regarding Elsevier's archiving and manuscript policies are encouraged to visit:

http://www.elsevier.com/copyright

Author's personal copy

Behavior Change Interventions Delivered by Mobile Telephone Short-Message Service

Brianna S. Fjeldsoe, BA, Alison L. Marshall, PhD, Yvette D. Miller, PhD

Context: The expansion and adoption of new methods of communication provide new opportunities for delivering health behavior change interventions. This paper reviews the current research examining mobile telephone short-message service (SMS) for delivering health behavior change interventions via text messages. This service has wide population reach, can be individually tailored, and allows instant delivery with asynchronous receipt, suggesting potential as a delivery channel for health behavior interventions.

Evidence acquisition: An electronic database search was conducted for studies published between January 1990 and March 2008. Studies were included in the review if they (1) evaluated an intervention delivered primarily via SMS, (2) assessed change in health behavior using pre–post assessment, and (3) were published in English in a peer-reviewed scientific journal.

Evidence synthesis: Of 33 studies identified, 14 met the inclusion criteria. Four of the 14 studies reviewed targeted preventive health behaviors (e.g., smoking cessation), and ten focused on clinical care (e.g., diabetes self-management). Positive behavior change outcomes were observed in 13 of the 14 reviewed studies. Intervention initiation (researcher or participant), SMS dialogue initiation, tailoring of SMS content, and interactivity were found to be important features of SMS-delivered interventions. Methodologic issues with current SMS research were also identified.

Conclusions: This review suggests that SMS-delivered interventions have positive short-term behavioral outcomes. Further research is required to evaluate interventions for preventive health behaviors that incorporate features found to affect behavioral outcomes and participant acceptance. The quality of studies in this emerging field of research needs to improve to allow the full potential of this medium to be explored.
(Am J Prev Med 2009;36(2):165–173) © 2009 American Journal of Preventive Medicine

Introduction

Recent reviews have focused on the effectiveness of health behavior change interventions delivered via telephone[1–4] and the Internet.[5–7] Researchers have suggested exploring other interactive delivery channels, such as mobile telephone short-message service (SMS),[8–12] but no systematic reviews have been reported to date. The aim of this paper is to review the preliminary evidence of health behavior change interventions delivered via SMS texting.

Mobile telephones and SMS are becoming integrated into virtually all aspects of society.[13–16] In the U.S. in 2007, approximately 7,000,000,000 SMS messages were sent every month.[17] In developed countries, use of SMS pervades all age groups,[9,15,18,19] cultures,[16] and socioeconomic backgrounds.[9,15] This service allows for instantaneous delivery of short messages (maximum 160 characters) directly to individuals at any time, place, or setting. These messages are asynchronous, meaning they can be accessed at a time that suits an individual. Customized SMS messages can be tailored to individuals, which is important given that personally tailored messages are more effective for health behavior change than untailored messages.[20–24] This medium also allows for seamless (and quantifiable) interaction between the participant and the interventionist, so that participant engagement with the intervention can be monitored and compared to exposure. Communication with SMS may also be more cost effective than other telephone or print-based interventions.[19,25]

The potential of SMS may be particularly significant among population groups most likely to use mobile telephones as their primary means of communication. The highest level of mobile telephone use is among adolescents, younger adults, socioeconomically disadvantaged populations, less educated young adults, and people who rent or frequently change addresses.[26–28]

From the School of Psychology, The University of Queensland (Fjeldsoe, Miller); and School of Public Health, Queensland University of Technology (Marshall), Brisbane, Australia

Address correspondence and reprint requests to: Brianna S. Fjeldsoe, BA, School of Psychology, The University of Queensland, St. Lucia, Qld, Australia 4072. E-mail: bcollins@psy.uq.edu.au; Alison L. Marshall, School of Public Health, Queensland University of Technology, Brisbane, Australia 4059. E-mail: alisonmarshall@qut.edu.au.

© 2009 American Journal of Preventive Medicine • Published by Elsevier Inc.
0749-3797/09/$–see front matter
doi:10.1016/j.amepre.2008.09.040

Author's personal copy

Further, a high level of mobile telephone use is associated with lower levels of self-rated health,[28] higher BMI,[29] and engaging in health-compromising behaviors.[30] Therefore, SMS presents a prime delivery channel for health behavior change interventions because it has high penetration in populations of lower sociodemographic position and populations with poorer health.

The application of SMS for behavioral intervention is new. However, there are established research agendas for using SMS to remind patients of scheduled medical appointments,[31–35] coordinate medical staff,[25] deliver medical test results,[36–38] and monitor patient side effects following treatment.[39] This review analyzes the application of SMS for delivering health behavior change interventions to establish what can be learned from research conducted to date and make recommendations for future research.

Evidence Acquisition

An electronic database search of MEDLINE, PubMed, ERIC, Web of Science, and PsycINFO was conducted for studies published between January 1990 and March 2008. The search terms included: *mobile telephone* or *cell phone*, *SMS* or *text message*, *health*, *health intervention*, and *behavior*. The search was limited to English. For inclusion in the review, studies had to evaluate an intervention delivered primarily via SMS to change a health behavior in any population group and have at least a pre–post design, but they were not required to have a control group. Because SMS research is in its early stages and because of the commercial nature of the medium, a number of studies have been published in so-called gray literature, such as magazines, newspapers, commercially funded reports, and editorial columns.[19,40,41] This review was limited to critically appraising studies published in peer-reviewed scientific journals.

Eligible articles were independently reviewed; any disagreements in review outcomes were discussed until consensus was reached among the three authors. During the independent review process, the following information was extracted from the eligible articles and tabulated: study design, research setting, sample size, participant recruitment process, participant retention rate throughout trial, main outcome, measurement method of main outcome, validity and reliability of measure, duration of intervention, how SMS dialogue was initiated, level of SMS interactivity between participant and researcher, dose of SMS messages received by participant, additional intervention methods, impact evaluation of main outcome, and process evaluation of SMS intervention. This list of study characteristics was based on the requirements of the Quality of Reporting of Meta-Analyses (QUOROM) statement.[42]

Each study was rated on the level of SMS interactivity between researcher and participant. These ratings ranged from nil to high and were based on the number of weekly/monthly SMS messages each participant was prescribed to send to researchers. The interactivity ratings were nil (no opportunity for participants to use SMS with researchers); low (<monthly SMS interaction); moderate (<weekly but ≥monthly SMS interaction); or high (≥weekly SMS interaction). Intervention outcomes were assessed as having a positive or neutral impact on behavioral outcomes, and where there was an impact, the study design (between groups or within group) and significance of effects were also assessed. To be able to compare outcomes across studies, effect sizes were calculated for studies that had a control group and reported sufficient data. Effect sizes were calculated based on Cohen's formula[43] and were interpreted according to Cohen's guidelines of <0.2 for a small effect size, 0.5 for a medium effect size, and >0.8 for a large effect size.

Thirty-three studies[44–76] used SMS as a delivery channel for health behavior change interventions, and 14[63–76] met the inclusion criteria for this review (Table 1). Reasons for exclusion included lack of pre–post study design,[44–57] SMS being used as an adjunct but not as the main method of intervention delivery,[58–60] and publication in languages other than English.[61,62] Numerous studies reported the development of SMS programs to change health behaviors.[44,48,50–55] The large number of developmental studies published in the past year indicates that research into behavior change via SMS is increasing in volume. Of the14 studies reviewed, four used SMS for preventive health behavior change (e.g., smoking cessation)[63–66] and ten used SMS to support ongoing clinical care behavior change (e.g., diabetes self-management).[67–76]

Evidence Synthesis

Study Designs

Six[63,65,67,69,72,73] of the 14 studies were RCTs (Table 1). One study was a clustered randomized comparative trial[74]; one was a randomized crossover trial[70]; and the other six[64,66,68,71,75,76] were single group, pre–post design studies. Intervention length ranged from 6 weeks[64] to 1 year.[67,69] None of the 14 studies collected follow-up data beyond the end of the intervention period. Most studies used objective and validated measures to assess intervention outcomes. Three studies[63,64,76] used self-report measures, and two of these studies[64,76] reported the validity and reliability of the survey. Sample sizes varied greatly among studies, ranging from 10[71] to 1705.[63] Five[63,69,70,73,74] of the 14 studies reported conducting sample size calculations to determine statistical power. Four[64,65,69,76] of the 14 studies implemented theory-based interventions. Theories used included Social Cognitive Theory,[69] Behavioral Self-Regulation Theory,[64] Relapse Prevention,[76] and a combination of social psychological theories.[65]

Study Outcomes

Significant, positive behavioral changes were observed in eight studies,[63,65,66,68,70–72] and a further five studies[64,67,69,73,74] demonstrated positive behavioral trends but did not have sufficient statistical power to demonstrate significance (Table 1). One study[76] showed no positive changes in behavior. Most clinical care studies did not evaluate the behaviors that were targeted in the intervention (e.g., physical activity, nutrition) and

Author's personal copy

Table 1. Behavioral interventions using short-message service (SMS)

Study	Behavior	Research design and participants	Intervention	Intervention effects
Preventive health behavior studies				
Rodgers (2005)[63]	Smoking cessation	Design: RCT Sample: 1705 smokers Setting: New Zealand public Recruitment: proactive Participant retention: 74% Main outcome measure: self-report—specific measure not reported	SMS initiation: researcher Format: daily, individually tailored SMS messages sent providing personalized smoking cessation advice, support, and distraction Supplementary materials: nil Duration: 26 weeks Interactivity: high[a]	Impact outcomes: more participants reported not smoking in the intervention group (28%) compared to the control group (13%) at 6 weeks ($p<0.0001$) and 12 weeks (29% vs 19%) ($p<0.0001$). At 26 weeks, there was no significant difference between groups ($p=0.4$). Process outcomes: high participant attrition rates in study evaluation (74% remained at 26 weeks) Calculated effect size: insufficient data reported Outcome overview: between group, significant, positive change in smoking cessation
Obermayer (2004)[64]	Smoking cessation	Design: pre–post pilot study Sample: 46 smokers Setting: colleges from the Washington DC area Recruitment: proactive Participant retention: 67% Main outcome measure: self-report—7-Day Smoking Reconstruction Form	SMS initiation: researcher Format: daily, individually tailored SMS sent to support smoking cessation; frequency of SMS tapered around nominated quit date Supplementary materials: interactive website with feedback and social support facility Duration: 6 weeks Interactivity: high	Impact outcomes: At 6 weeks point, 43% of participants had made at least one 24-hour attempt to quit, and 22% had quit based on a 7-day criterion. Process outcomes: moderately high use and acceptance of program. Satisfaction with program differed between quitters (M=4.3) and nonquitters (M=3.2) ($p<0.01$). Calculated effect size: NA Outcome overview: within group, positive change
Hurling (2007)[65]	Physical activity	Design: RCT Sample: 77 healthy adults Setting: Bedfordshire, United Kingdom Recruitment: proactive Participant retention:100% Main outcome measure: objective measure—accelerometer	SMS initiation: researcher Format: tailored SMS offering solutions for perceived barriers and schedule reminders for weekly physical activity Supplementary materials: email and interactive website with feedback facility; wrist accelerometers for self-monitoring Duration: 9 weeks Interactivity: moderate	Impact outcomes: At 9 weeks, the intervention group showed significantly more moderate-intensity physical activity than the control group ($p=0.02$). Average increase in the intervention group for moderate-intensity physical activity was 2 hours, 18 minutes per week (accelerometer data). Process outcomes: SMS-specific outcomes not reported. Website use was high (M=2.9 log-ons per week). Calculated effect size: 0.82 (moderate-intensity physical activity) Outcome overview: between group, significant, positive change in physical activity
Joo (2007)[66]	Anti-obesity behavior modification	Design: pre–post design Sample: 927 healthy adults Setting: Korean public health clinics Recruitment: active Participant retention: 47% Main outcome measure: objective measure—scales and stadiometer	SMS initiation: researcher Format: weekly, untailored behavior change SMS for nutrition and exercise Supplementary materials: initial consult with dietitian, weekly brochures mailed to participants, free access to dumbbells and pedometers Duration: 12 weeks Interactivity: moderate	Impact outcomes: At 12 weeks, there were mean reductions in weight (1.6 kg, $p<0.001$), waist circumference (4.3 cm, $p<0.001$) and BMI (0.6 kg/m^2, $p<0.001$) in those who completed the 12-week program. Process outcomes: 71% of participants who completed the 12-week program thought it was effective. More than half of originally recruited participants did not complete the program. Calculated effect size: NA Outcome overview: within group, significant, positive change in weight reduction
Clinical care studies				
Vahatalo (2004)[67]	Diabetes self-management	Design: nonparallel, non-RCT Sample: 200 patients with Type 1 diabetes Setting: Diabetes Outpatient Clinic of Turku Health Centre, Finland Recruitment: active Participant retention:100% Main outcome measure: objective measure—HbA1c	SMS initiation: participant Format: participants sent plasma glucose test results and received tailored feedback from doctors. Supplementary materials: nil Duration: 12 months Interactivity: high- moderate	Impact outcomes: Glycemic control (HbA1c) did not change in intervention patients. A subsample of seven high users (>20 SMS/week) showed a decrease in HbA1c resulting in a 0.75% difference ($p=0.09$). Insulin dose of intervention patients increased significantly ($p<0.05$). Process outcomes: low patient interaction with SMS program Calculated effect size: 0.09 (HbA1c) 0.59 (HbA1c—high users) Outcome overview: between group, positive change in glycemic control

(continued on next page)

Author's personal copy

Table 1. Behavioral interventions using short-message service (SMS) *(continued)*

Study	Behavior	Research design and participants	Intervention	Intervention effects
Kwon (2004)[68]	Diabetes self-management	Design: pre–post design Sample: 185 diabetic patients Setting: St. Mary's Hospital, Korea Recruitment: proactive Participant retention: 72% Main outcome measure: objective measure— HbA1c	SMS initiation: participant Format: participants sent blood glucose level, medication, number of meals, and exercise to doctor. Doctor sent individualized management SMS. Supplementary materials: interactive website with feedback facility. Consultations with dietitians were available to all participants. Duration: 3 months Interactivity: moderate	Impact outcomes: Mean HbA1c improved from 7.5 (±1.5) to 7.0 (±1.1) after the intervention (p=0.003). Lipid profiles also improved after the intervention. Process outcomes: participant compliance with SMS program was 72%. Satisfaction with SMS program was good. Calculated effect size: NA Outcome overview: within group, significant, positive change in HbA1c levels
Franklin (2006)[69]	Diabetes self-management	Design: RCT (three groups—control, CIT + SweetTalk, IIT + SweetTalk) Sample: 92 pediatric patients with Type 1 diabetes Setting: Scottish pediatric clinic Recruitment: proactive Participant retention: 98% Main outcome measure: objective measure— HbA1c	SMS initiation: researcher Format: SweetTalk program sent daily SMS providing personalized goal-specific prompts tailored to age, gender, and insulin regimen Supplementary materials: adapted insulin therapy for IIT group; goal-setting consult for CIT and IIT groups Duration: 12 months Interactivity: high	Impact outcomes: At 12 months, HbA1c did not change in the control or CIT groups, but did change in the IIT group (9.2±2.2%, CI=–1.9, 0.5, p<0.001). SweetTalk was associated with improvements in diabetes self-efficacy (p<0.003) and self-reported adherence to insulin regimen (p<0.042). Process outcomes: 72% felt SweetTalk helped manage their diabetes; 90% wanted to continue receiving SMS. Calculated effect size: 0.12 (HbA1c—CIT) 0.56 (HbA1c—IIT) Outcome overview: between group, positive change in HbA1c levels
Rami (2006)[70]	Diabetes self-management	Design: randomized crossover trial Sample: 36 adolescents with Type 1 diabetes Setting: diabetes clinic, Vienna, Austria Recruitment: proactive Participant retention:100% Main outcome measure: objective measure— HbA1c	SMS initiation: participant Format: participants sent daily blood glucose level, insulin doses and carbohydrate intake to monitoring center via a GPRS. Monitoring center sent 1 SMS per week with individualized or generic advice depending on need for treatment changes. Supplementary materials: paper diary of symptoms Duration: 3 months Interactivity: high	Impact outcomes: At 3 months, HbA1c significantly improved during the intervention phase for both groups (p<0.05). Process outcomes: There were technical problems with GPRS access for some participants. Most participants rated the program as useful and reported it took less than 1 minute to send their daily data via SMS. Calculated effect size: insufficient data reported Outcome overview: between group, significant, positive change in HbA1c levels
Kollman (2007)[71]	Diabetes self-management	Design: pre–post pilot study Sample: 10 patients with Type 1 diabetes Setting: diabetes clinic, Vienna, Austria Recruitment: proactive Participant retention:100% Main outcome measure: objective measure— HbA1c	SMS initiation: participant Format: participants sent daily blood glucose level, insulin doses, nutrition and physical activity data to monitoring center. Monitoring center generated individualized management SMS. Supplementary materials: interactive website with feedback facility Duration: 3 months Interactivity: high	Impact outcomes: At 3 months, there was a significant improvement in metabolic control (from 7.9% to 7.5%, p=0.02) and a nonsignificant improvement in average blood glucose level. Process outcomes: average of 14 parameters transmitted per day per participant Calculated effect size: NA Outcome overview: within group, significant, positive change in metabolic control
Kim (2007)[72]	Diabetes self-management	Design: RCT Sample: 60 patients with Type 2 diabetes Setting: endocrinology department of hospital, South Korea Recruitment: proactive Participant retention: 85% Main outcome measure: objective measure— HbA1c	SMS initiation: researcher Format: participants sent data about blood glucose level and insulin doses via a website. Staff sent weekly SMS messages with individualized management strategies. Supplementary materials: interactive website with feedback facility Duration: 12 weeks Interactivity: moderate	Impact outcomes: At 12 weeks, there was a significant difference in mean HbA1c decrease between the intervention group (1.15% decrease) and control group (0.07% decrease) (p=0.005). Process outcomes: not reported Calculated effect size: 0.75 (HbA1c) Outcome overview: between group, significant, positive change in HbA1c levels

(continued on next page)

Author's personal copy

Table 1. *(continued)*

Study	Behavior	Research design and participants	Intervention	Intervention effects
Ostojic (2005)[73]	Asthma self-management	Design: RCT Sample: 16 asthma patients Setting: Croatian asthma clinic Recruitment: active Participant retention:100% Main outcome measure: objective measure— PEF	SMS Initiation: participant Format: Participants sent daily PEF measures to doctor and received reply of tips and education. Supplementary materials: consultation with medical staff, paper diary to record asthma symptoms, PEF Duration: 16 weeks Interactivity: moderate	Impact outcomes: At 16 weeks, no difference in PEF between groups at any time of the day (morning, afternoon, or evening). PEF variability was significantly reduced in intervention group (16.12%) compared to the control group (27.24%) (p= 0.049). Control group had significantly higher scores for coughs (p<0.05) and night symptoms (p<0.05) than intervention group. Process outcomes: Participant compliance with SMS transmission of PEF was 99%. Calculated effect size: 1.38 (PEF variability) Outcome overview: between group, positive change in PEF
Marquez (2004)[74]	Hypertension medication compliance	Design: randomized cluster comparative trial Sample: 104 patients with uncontrolled HTN Setting: 26 primary healthcare centers in Spain Recruitment: active Participant retention: 64% Main outcome measure: objective measure—count tablets and BP	SMS initiation: researcher Format: 2 SMS messages/week sent to participants about "good health," nutrition, medication reminders, and advice Supplementary materials: printed information about HTN Duration: 6 months Interactivity: nil	Impact outcomes: At 6 months, there were no significant differences in medication compliance between intervention (89.5%) and control groups (78.9%). There were no significant differences in blood pressure between groups at 6 months, but positive trend in intervention group. Process outcomes: none reported Calculated effect size: 0.50 (medication compliance) 0.09 (systolic BP); 0.22 (diastolic BP) Outcome overview: between group, positive change for BP control
Logan (2007)[75]	Hypertension self-management in diabetic patients	Design: Pre–post pilot study Sample: 33 patients with Type 2 diabetes and uncontrolled ambulatory BP Setting: 25 family physicians in Toronto and U.S. Recruitment: proactive Participant retention: 94% Main outcome measure: objective measure—BP	SMS initiation: participant Format: participants reported 2 consecutive BP readings twice daily for 2 days per week to local physician. Tailored recommendations were sent to patients. Supplementary materials: nil Duration: 4 months Interactivity: high	Impact outcomes: Both ambulatory BP (p<0.001) and 2-week average home BP (0=0.005) showed significant improvement following pilot study. Process outcomes: Number of BP reports was higher than requested of the patients but did drop over the 4 months (11.6 per week to 10.5 per week). Calculated effect size: NA Outcome overview: within group, significant, positive change in BP
Robinson (2006)[76]	Bulimia nervosa outpatient care	Design: pre–post design Sample: 21 patients diagnosed with bulimia nervosa Setting: London outpatient clinic Recruitment: proactive Participant retention: 43% Main outcome measure: self-report—Short Evaluation of Eating Disorders	SMS initiation: participant Format: Participants sent weekly updates of bulimic symptoms and received a tailored SMS offering support. Supplementary materials: nil Duration: 6 months Interactivity: low	Impact outcomes: no significant symptom change between pre- and post-intervention Process outcomes: Program use was low and attrition rates were high. Calculated effect size: NA Outcome overview: within group, no change

[a]High interactivity: ≥weekly SMS interaction; moderate interactivity: <weekly but ≥monthly SMS interaction; low interactivity: <monthly SMS interaction
BP, blood pressure; CIT, conventional insulin therapy; GPRS, General Packet Radio Service; HTN, hypertension; IIT, intensive insulin therapy; NA, not applicable for study design; PEF, peak expiratory flow

Author's personal copy

instead evaluated the health outcomes of the intervention (e.g., blood glucose levels, peak expiratory flow).

Of the eight studies[63,65,67,69,70,72–74] with a control group, six[65,67,69,72–74] reported sufficient data to enable effect sizes to be calculated. The range of effect sizes was 0.09[67] to 1.38[73] (Table 1). Based on Cohen's guidelines,[43] four of the six calculated effect sizes were classified as medium[72,74] or large effects.[65,73] The calculated effect sizes for the other two studies were classified as small (0.09[67] and 0.12[69]). However, both of these studies reported stronger findings for a subgroup of participants who either were more actively engaged in the SMS intervention[67] or received a more intensive complimentary treatment.[69] When effect sizes were calculated for these subgroups, both had effect sizes classified as medium (0.59[67] and 0.56[69]).

Process outcomes were poorly evaluated in most studies. Participant retention ranged from 43% to 100% (Table 1). There was great variability in participant compliance and acceptance of SMS programs across studies. One study reported that participants wanted to continue the SMS program after the trial had been completed.[69]

Specific SMS Characteristics

Mode of intervention initiation varied among studies. Twelve programs[65–76] were initiated by a face-to-face meeting with a health professional; the others used SMS to initiate the program and gain participant consent,[63] or an interactive website.[64] There were also differences in the initiation of SMS dialogue. In seven studies,[63–66,69,72,74] the researchers initiated the SMS dialogue and participants were able to respond (researcher-initiated technique). In the other seven studies,[67,68,70,71,73,75,76] participants initiated the SMS dialogue and then the researchers responded (participant-initiated technique). There were no clear differences in intervention outcomes based on SMS dialogue initiation. However, all the preventive health behavior studies used researcher-initiated techniques, and most of the tertiary-level interventions used participant-initiated techniques.

The frequency of SMS transmission reflected the expected frequency of the targeted behavior (e.g., smoking [5/day], physical activity [5/week]) for all but three studies.[66,72,74] Most of the interventions provided personally tailored SMS, except two studies[66,74] that used bulk, untailored SMS. Tailoring variables included participant's name or nickname, nominated support person's name, age, gender, behavioral history, behavioral preferences, behavioral goals, behavioral barriers, previous SMS responses, and medical status. The two studies[66,74] that used untailored SMS were in the top three for highest participant attrition.

Some studies supplemented SMS-delivered components with other intervention strategies or materials, such as interactive websites,[64,65,68,71,72] a paper diary to record symptoms,[70,73] consultation sessions with health professionals,[66,68,69,73] or printed materials.[66,74] Evaluation and reporting of the uptake and behavioral outcomes of these separate intervention strategies were poor.

Most studies allowed moderate to high SMS interaction between participants and researchers. One study[74] had no SMS interaction with participants. However, it is difficult to compare interaction levels across studies because some interventions offered other channels of interaction (e.g., websites or clinical visits).

Discussion

This review draws together the preliminary evidence of delivering health behavior change interventions via SMS. Most studies conducted to date have focused on clinical care interventions, using SMS as a reminder to increase adherence to treatment programs among sick individuals. Fewer studies have focused on promoting preventive health behaviors to healthy individuals through SMS. Of the 14 SMS reviewed interventions, 13 demonstrated positive behavior changes, although some studies were too statistically underpowered to show significant results.

It is important at this early stage of research to acknowledge the limited number of high-quality SMS intervention studies. The broad range of study designs used and the varying use of specific SMS characteristics in interventions limit the conclusions that can be drawn from this review but at the same time highlight the importance of improving the quality and rigor of future research in this area.

Future studies should use adequate sample sizes to provide sufficient statistical power for detecting hypothesized effects and should explicitly report the calculations performed to estimate power. Although it is recognized that some of the reviewed studies were pilot tests or feasibility studies, positive effects need to be rigorously evaluated in larger follow-up trials that test the efficacy of the intervention in more-representative samples. Assessment of the maintenance of behavioral effects after the intervention period is another important focus for future research. Future studies should also report on process measures associated with intervention delivery, such as number of sent SMS messages, number of SMS replies, how participants treated received SMS messages, and how stored SMS messages are treated. In some reviewed studies, it was also difficult to determine the relative impact of the SMS strategy because it was evaluated as an adjunct rather than as a comprehensive strategy. Future research should explore SMS as a primary means of intervention and report on appropriate process outcomes.

A strength of the current research is the use of objective and validated measures. This is important to ensure that the behavioral outcomes of SMS-delivered

Author's personal copy

interventions are accurately assessed, and this should be maintained in future research. A major evaluation problem in the current literature is the lack of assessment of intervention effects on targeted behaviors. Most clinical care studies failed to measure the behaviors targeted in the intervention, even though these outcomes are more proximal to intervention exposure than health outcomes. This has serious consequences as it prevents assessment of the intervention effects on the targeted behaviors that are hypothesized to cause subsequent health benefits.

Future studies should explicitly describe the theoretical constructs being targeted in interventions. This will assist further testing and development of behavior change theory as it applies to this new medium. The lack of theory-based interventions in this review may reflect the current focus of SMS interventions on clinical care rather than on preventive health behavior change.

Another area for future research is the variations in the use of specific SMS characteristics across interventions. Characteristics of SMS of interest in the current literature include mode of intervention initiation, initiation of SMS dialogue, tailoring of SMS content, and the opportunity for SMS interaction between participants and researchers. Because this research field is in the early stages of development and because of the study designs used, it is difficult to determine the impacts that these specific SMS characteristics may have on behavioral outcomes. However, it is important to acknowledge that these issues are specific to SMS interventions, and if this field of research is to progress, the importance of these SMS characteristics needs to be explored further.

Intervention initiation methods differed between clinical care interventions and preventive health behavior interventions. Clinical care interventions involve patients already engaged in the health system because of illness or disease and thus focus on better managing their treatment. As such, clinical care interventions are often initiated face-to-face because patients are consulting with health professionals. In contrast, preventive health behavior interventions require delivery channels that can reach mass populations of healthy individuals who may not be engaged with health professionals. Two of the preventive health behavior studies in this review demonstrated methods of intervention initiation that could be feasible for population-wide dissemination—a registration website[64] and registration SMS.[63] In both cases, these initiation methods provided sufficient communication to allow for informed participant consent, personal information for tailoring SMS, and instructions for how to use the program.

Initiation of the SMS dialogue also differed between clinical care and preventive health behavior interventions. All the preventive health behavior interventions in this review used researcher-initiated SMS dialogue, whereas the majority of the clinical care interventions used participant-initiated techniques. Participants in preventive health behavior interventions may not be motivated to initiate dialogue because they are healthy, unlike participants in need of clinical care intervention who are accustomed to regularly reporting to health professionals about their health status. Initiation methods may play an important role in participants' perceptions of personal invasion and behavioral control, which may affect behavioral outcomes. Therefore, the SMS initiation method may be an important intervention element to explore further in terms of relative behavior change outcomes.

It is well established that tailored health messages are more engaging and effective at changing behavior than untailored, bulk messages.[21–24] All but two studies in this review used tailored SMS. The two studies[66,74] using untailored SMS targeted a wide range of behavioral changes (e.g., physical activity, nutrition, medication compliance, smoking, alcohol consumption) and were among the studies with the highest participant attrition. This finding may support the notion that untailored health messages are less engaging for participants. Because participant engagement and retention are critical factors in successful behavior change research, it is important to further investigate the impact of tailoring content in SMS research.

Interactivity and responsiveness to participants' needs, a potential feature of SMS-delivered interventions, may improve the outcomes of behavior change interventions.[11] One reviewed study[74] did not allow interaction with participants, and that study had poor participant retention, which may have been associated with poor participant engagement. Interactivity of interventions was poorly reported and was often difficult to quantify because of the potential influence of other forms of interaction with participants (e.g., websites). The effect of interactivity of SMS-delivered interventions needs to be explored further to determine the optimal level of interaction for successful behavior change.

Although first-generation studies have demonstrated the potential of delivering health behavior change interventions via SMS, there is still much to be learned about optimizing and enhancing this intervention channel. Research on the effects of specific SMS characteristics is now required to better understand the potential of this new medium. Consideration of the methodologic issues highlighted in this review is needed to improve the quality of research in this field. These issues need to be considered promptly to allow scientific knowledge to develop at a pace in keeping with the rapid advancement of SMS technologic capabilities and reach.

Author's personal copy

No financial disclosures were reported by the authors of this paper.

References

1. Chaudhry S, Phillips C, Stewart S, et al. Telemonitoring for patients with chronic heart failure: a systematic review. J Card Fail 2007;13:56–62.
2. Eakin E, Lawler S, Vandelanotte C, Owen N. Telephone interventions for physical activity and dietary behavior change: a systematic review. Am J Prev Med 2007;32:419–34.
3. Jaana M, Pare G. Home telemonitoring of patients with diabetes: a systematic assessment of observed effects. J Eval Clin Prac 2007;13:242–53.
4. Revere D, Dunbar P. Review of computer-generated outpatient health behavior interventions: clinical encounters 'in absentia.' J Am Med Inform Assoc 2001;8:62–79.
5. Evers K, Prochaska J, Driskell M, Cummins C, Velicer W. Strengths and weaknesses of health behavior change programs on the internet. J Health Psych 2003;8:63–70.
6. Marcus B, Nigg C, Reibe D, Forsyth A. Interactive communication strategies: implications for population-based physical activity promotion. Am J Prev Med 2000;19:121–6.
7. Vandelanotte C, Spathonis K, Eakin E, Owen N. Website-delivered physical activity interventions: a review of the literature. Am J Prev Med 2007;33: 54–64.
8. Patrick K. Information technology and the future of preventive medicine: potential, pitfalls and policy. Am J Prev Med 2000;19:132–5.
9. Rice R, Katz J. Comparing internet and mobile phone usage: digital divides of usage, adoption and dropouts. Telecommunications Policy 2003;27:597–623.
10. Neuhauser L, Kreps G. Rethinking communication in the e-Health era. J Health Psychol 2003;8:7–22.
11. Atkinson NL, Gold RS. The promise and challenge of eHealth interventions. Am J Health Behav 2002;26:494–503.
12. Patrick K, Griswold WG, Raab F, Intille SS. Health and the mobile phone. Am J Prev Med 2008;35:177–81.
13. Katz J. Machines that become us: the social context of personal communication technology. New Brunswick New Jersey: Transaction Publishers, 2003.
14. Hamill L, Lasen A. Mobile world: past, present and future. Springer: USA, 2005.
15. Ling R. The mobile connection: the cell phone's impact on society. San Francisco: Morgan Kaufmann Publishers, 2004.
16. Goggin G. Cell phone culture: mobile technology in everyday life. New York: Routledge, 2006.
17. Cellular Telecommunications & Internet Association. Semi-Annual Wireless Industry Survey. Washington: 2006.
18. Puro J. Finland: a mobile culture. In: Katz J, Aarkhus M, eds. Perpetual contact. Cambridge: CUP, 2002, 19–30.
19. Atun R, Sittampalam S. A review of the characteristics and benefits of SMS in delivering healthcare. The Role of Mobile Phones in Increasing Accessibility and Efficiency in Healthcare Report. Vodafone: 2006.
20. Dijkstra A, De Vries H. The development of computer-generated tailored interventions. Patient Educ Couns 1999;36:193–203.
21. Bull F, Holt C, Kreuter M, Clark E, Scharff D. Understanding the effects of printed health education materials: which features lead to which outcomes? J Health Commun 2001;6:265–79.
22. Suggs LS. A 10-year retrospective of research in new technologies for health communication. J Health Commun 2006;11:61–74.
23. Trevena L, Davey H, Barratt A, Butow P, Caldwell P. A systematic review on communicating with patients about evidence. J Eval Clin Pract 2006;12:13–23.
24. Ryan P, Lauver D. The efficacy of tailored interventions. J Nurs Scholarsh 2002;34:331–7.
25. Sherry E, Collordi B, Warnke P. Short messaging service (SMS): a useful communication tool for surgeons. Aust N Z J Surg 2002;72:369.
26. Franklin V, Waller A, Pagliari C, Greene S. Sweet talk: text messaging support for intensive insulin therapy for young people with diabetes. Diabetes Technol Ther 2003;5:991–6.
27. Faulkner X, Culwin F. When fingers do the talking: a study of text messaging. Interacting Comput 2005;17:167–85.
28. Koivusilta K, Lintonen T, Rimpela A. Orientations in adolescent use of information and communication technology: a digital divide by sociodemographic background, educational career and health. Scandinavian J Public Health 2007;35:95–103.
29. Lajunen H, Keski-Rahkonen A, Pulkkinen L, Rose R, Rissanen A, Kaprio J. Are computer and cell phone use associated with body mass index and overweight? A population study among twin adolescents. BMC 2007;7: e1–8.
30. Koivusilta K, Lintonen T, Rimpela A. Intensity of mobile phone use and health compromising behaviours—how is information and communication technology connected to health-related lifestyle in adolescence? J Adolesc 2005;28:35–47.
31. Bos A, Hoogstraten J, Prahl-Andersen B. Failed appointments in an orthodontic clinic. Am J Orthod Dento Orthop 2005;127:355–7.
32. Downer SR, Meara JG, DaCosta A. Use of SMS text messaging to improve outpatient attendance. MJA 2005;183:366–8.
33. Milne R, Horne M, Torsney B. SMS reminders in the UK National Health Service: an evaluation of its impact on no-shows at hospital out-patient clinics. Health Care Manage Rev 2006;31:130–6.
34. Vilella A, Bayas J, Diaz M, et al. The role of mobile phones in improving vaccination rates in travelers. Prev Med 2004;38:503–9.
35. Cohen C, Coyne K, Mandalia S, Waters A, Sullivan A. Time to use text reminders in genitourinary medicine clinics. Int J STD AIDS 2008;19:12–3.
36. Pal B. The doctor will text you now; is there a role for the mobile telephone in health care? BMJ 2003;326:607.
37. Tomnay JE, Pitts MK, Fairley CK. New technology and partner notification—why aren't we using them? Int J STD AIDS 2005;16:19–22.
38. Menon-Johansson AS, McNaught F, Mandalia S, Sullivan AK. Texting decreases the time to treatment for genital Chlamydia trachomatis infection. STI 2006;82:49–51.
39. Weaver A, Young A, Rowntree J, et al. Application of mobile phone technology for managing chemotherapy-associated side-effects. Annals Oncol 2007;18:1887–92.
40. Dayani A. New text scheme for mums-to-be. Evening Mail: 2005.
41. Neville R, Greene A, McLeod J, Tracy A, Surie J. Mobile phone text messaging can help young people manage asthma. BM J 2002;325:600.
42. Moher D, Cook D, Eastwood S, Olkin I, Rennie D, Stroup D. Improving the quality of reports of meta-analyses of randomized controlled trials: the QUOROM statement. Lancet 1999;354:1896–900.
43. Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. New Jersey: Lawrence Erlbaum Associates, 1988.
44. Ferrer-Roca O, Cardenas A, Diaz-Cardama A, Pulido P. Mobile phone text messaging in the management of diabetes. J Telemedicine Telecare 2004;10:282–6.
45. Gammon D, Arsand E, Walseth O, Andersson N, Jenssen M, Taylor T. Parent-child interaction using a mobile and wireless system for blood glucose monitoring. J Med Internet Res 2005;7:e57.
46. Wangberg S, Arsand E, Andersson N. Diabetes education via mobile text messaging. J Telemedicine Telecare 2006;12:s55–s56.
47. Anjoh J, Moldrup C. Feasibility of collecting diary data from asthma patients through mobile phones and SMS (Short Message Service): response rate analysis and focus group evaluation from a pilot study. J Med Internet Res 2004;6:e42.
48. Bellazzi R, Arcelloni M, Ferrari P, et al. Management of patients with diabetes through information technology: tools for monitoring and control of the patients' metabolic behavior. Diab Tech Therap 2004;6: 567–78.
49. Hung S, Tseng H, Tsai W, Lin H, Cheng J, Chang Y. Care for asthma via mobile phone (CAMP). Stud Health Technol Inform 2007;126:137–43.
50. Gibson F, Miller M, Kearney N. Technology into practice: young people's, parent's and nurses' perceptions of WISECARE+. Paed Nurs 2007;19:31–4.
51. Pinnock H, Slack R, Pagliari C, Price D, Sheikh A. Understanding the potential role of mobile phone-based monitoring on asthma self-management: qualitative study. Clin Exper Allergy 2007;37:794–802.
52. Cleland J, Cladow J, Ryan D. A qualitative study of the attitudes of patients and staff to the use of mobile phone technology for recording and gathering asthma data. J Telemed Telecare 2007;13:85–9.
53. Carroll A, Marrero DE, Downs S. The HealthPia GlucoPack diabetes phone: a usability study. Diab Tech Therap 2007;9:158–64.
54. Halifax N, Cafazzo J, Irvine J, Hamill M, Rizo C, McIssac W. Telemanagement of hypertension: a qualitative assessment of patient and physician preferences. Can J Cardiol 2007;23:591–4.
55. Boland P. The emerging role of cell phone technology in ambulatory care. J Ambulatory Care Manage 2007;30:126–33.

Author's personal copy

56. Trudel M, Cafazzo J, Hamill M, et al. A mobile phone based remote patient monitoring system for chronic disease management. Medinfo 2007;12:167–71.
57. Bauer S, Percevic R, Okon E, Meermann R, Kordy H. Use of text messaging in the aftercare of patients with Bulimia Nervosa. Eur Eat Disorders Rev 2003;11:279–90.
58. Fairley CK, Levy R, Rayner CR, et al. Randomized trial of an adherence program for clients with HIV. Int J STD AIDS 2003;14:805–9.
59. Wilkins A, Mak D. . . . Sending out an SMS: an impact and outcome evaluation of the Western Australian Department of Health's 2005 Chlamydia campaign. Health Promotion J Aust 2007;18:113–20.
60. Vidrine D, Arduino R, Lazev A, Gritz E. A randomized trial of a proactive cellular telephone intervention for smokers living with HIV/AIDS. AIDS 2006;20:253–60.
61. Kubota A, Fujita M, Hatano Y. Development and effects of a health promotion program utilizing the mail function of mobile phones. Jap J Public Health 2004;51:862–73.
62. Yeong S, Siun Lim S. The effects of a weight control program with competence. Taehan Kanho Hakhoe Chi 2007;37:1177–83.
63. Rodgers A, Corbett T, Riddell T, Wills M, Lin R, Jones M. Do u smoke after txt? Results of a randomized trial of smoking cessation using mobile phone text messaging. Tob Control 2006;14:255–61.
64. Obermayer J, Riley W, Asif O, Jean-Mary J. College smoking-cessation using cell phone text messaging. J Am Coll Health 2004;53:71–8.
65. Hurling R, Catt M, DeBoni M, et al. Using Internet and mobile phone technology to deliver an automated physical activity program: randomized controlled trial. J Med Internet Res 2007;9:e7.
66. Joo N, Kim B. Mobile phone short message service messaging for behavior modification in a community-based weight control programme in Korea. J Telemedicine Telecare 2007;13:416–20.
67. Vahatalo MA, Virtamo HE, Viikari JS, Ronnemaa T. Cellular phone transferred self blood glucose monitoring: prerequisites for positive outcome. Practical Diab Int 2004;21:192–4.
68. Kwon H, Cho J, Kim H, et al. Development of web-based diabetic patient management system using short message service (SMS). Diabetes Res Clin Pract 2004;66:s133–s137.
69. Franklin V, Waller A, Pagliari C, Greene S. A randomized controlled trial of SweetTalk, a text-messaging system to support young people with diabetes. Diabet Med 2006;23:1332–8.
70. Rami B, Popow C, Horn W, Waldhoer T, Schober E. Telemedicine support to improve glycemic control in adolescents with Type 1 Diabetes Mellitus. Eur J Pediatr 2006;165:701–5.
71. Kollman A, Riedl M, Kastner P, Schreier G, Ludcik B. Feasibility of a mobile phone-based data service for functional insulin treatment of Type 1 Diabetes Mellitus patients. J Med Internet Res 2007;9:e36.
72. Kim H. A randomized controlled trial of a nurse short-message service by cellular phone for people with diabetes. Int J Nurs Stud 2007;44:687–92.
73. Ostojic V, Cvoriscec B, Ostojic SB, Reznifoff D, Stripic-Markovic A, Tudjman Z. Improving asthma through telemedicine: a study of short-message service. Telemed J E Health 2005;11:28–35.
74. Marquez Contreras E, Figuera von Wichmann M, Guillen V, Figueras M, Balana M, Naval J. Effectiveness of an intervention to provide information to patients with hypertension as short text messages of reminders sent to their mobile phone. Atencion Primaria 2004;34:399–405.
75. Logan A, McIsaac W, Tisler A, et al. Mobile phone-based remote patient monitoring system for management of hypertension in diabetic patients. Am J Hypertension 2007;20:942–8.
76. Robinson S, Perkins S, Bauer S, Hammond N, Treasure J, Schmidt U. Aftercare intervention through text messaging in the treatment of Bulimia Nervosa-feasibility study. Int J Eat Disord 2006;39:633–8.

Did you know?
You can personalize the *American Journal of Preventive Medicine* website to meet your individual needs.
Visit www.ajpm-online.net today to see what else is new online!

BMC Public Health

STUDY PROTOCOL Open Access

Moving MobileMums forward: protocol for a larger randomized controlled trial of an improved physical activity program for women with young children

Alison L Marshall[1], Yvette D Miller[1,2*], Nicholas Graves[1], Adrian G Barnett[1] and Brianna S Fjeldsoe[3]

Abstract

Background: Women with young children (under 5 years) are a key population group for physical activity intervention. Previous evidence highlights the need for individually tailored programs with flexible delivery mechanisms for this group. Our previous pilot study suggested that an intervention primarily delivered via mobile phone text messaging (MobileMums) increased self reported physical activity in women with young children. An improved version of the MobileMums program is being compared with a minimal contact control group in a large randomised controlled trial (RCT).

Methods/design: This RCT will evaluate the efficacy, feasibility and acceptability, cost effectiveness, mediators and moderators of the MobileMums program. Primary (moderate vigorous physical activity) and secondary (intervention implementation data, health service use costs, intervention costs, health benefits, theoretical constructs) outcomes are assessed at baseline, 3 months (end of intervention) and 9 months (following 6 month no contact: maintenance period).

The intervention commences with a face to face session with a behavioural counsellor to initiate rapport and gather information for tailoring the 12 week text message program. During the program participants also have access to a: MobileMums Participant Handbook, MobileMums refrigerator magnet, MobileMums Facebook© group, and a MobileMums website with a searchable, on line exercise directory. A nominated support person also receives text messages for 12 weeks encouraging them to offer their MobileMum social support for physical activity.

Discussion: Results of this trial will determine the efficacy and cost effectiveness of the MobileMums program, and the feasibility of delivering it in a community setting. It will inform the broader literature of physical activity interventions for women with young children and determine whether further investment in the translation of the program is warranted.

Trial registration: The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12611000481976).

Keywords: Text message, SMS, Mobile telephone, Postnatal women, Exercise, Intervention

* Correspondence: yvette.miller@qut.edu.au
[1]Queensland University of Technology, Institute of Health and Biomedical Innovation, School of Public Health and Social Work, Faculty of Health, Brisbane, Australia
[2]The University of Queensland, School of Psychology, Brisbane, Australia
Full list of author information is available at the end of the article

BioMed Central

© 2013 Marshall et al.; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Background

Evidence is constantly emerging to support the role of physical activity in the prevention and management of chronic disease [1]. Most developed countries now have public health guidelines for promoting physical activity in adults, yet surveillance data in most countries reveal low guideline compliance [e.g. [2,3]. In Australia, most adults report insufficient levels of physical activity and this guideline deficit is greater in women (62%) than in men (58%) [4]. Australian women with young children (under 5 years old) are less active than women of the same age without children [5] and women with older children [6-8].

Importantly, most women with young children believe in the health benefits that can accumulate from regular physical activity [9-11]. However, previous studies have shown that women with young children lack confidence in being able to include physical activity in their daily lives. Their confidence is eroded by perceived barriers (such as limited access to child care or a lack of instrumental support from their partner) and ideological influences (like their sense of commitment to care for others which leaves them with less time to pursue individual needs) [10-12]. These issues may be overcome by programs that respect women's multiple roles and provide them with specific cognitive and behavioural skills to overcome barriers and increase their confidence to prioritise physical activity.

Theory-based, individually tailored programs have demonstrated success at increasing physical activity of women with young children [10,13-16]. Previous interventions in this population group have been predominantly delivered by face-to-face contact in either group [13,15,17,18] or individual sessions [16,19]. Although generally effective at increasing physical activity, the evidence from these trials suggests that the requirement for regular face-to-face contact may reduce program attendance [17,20-22]. More recently, researchers have started evaluating broad reach interventions in this population group, using telephone counselling and/or email contact to increase physical activity [23,24]. Emerging research using these mediated (non face-to-face) delivery modes is critical to advancing physical activity interventions for women with young children because it can address issues such as: reaching women from less advantaged backgrounds and across geographic areas; reducing the burden on women accessing programs in structured face-to-face settings; and importantly for public health, potentially reducing the cost of program delivery.

We have spent several years developing MobileMums, a theory-based, tailored physical activity program that responds to the needs of women with young children and is primarily delivered via mobile telephone text messaging [25-27]. In our previous pilot study we found that MobileMums produced short-term (end-of-intervention) increases in the frequency of self-reported moderate-vigorous physical activity [27]. The women in the pilot study were engaged with the program and satisfied that it supported them to increase their physical activity [27]. However, this previous trial: was not adequately powered for examining effects on minutes per week of moderate-vigorous physical activity, did not include a cost-effectiveness analysis, did not include objective measurement of physical activity, and did not assess the longer-term maintenance of the intervention after contact finished. This paper describes the methods of a trial designed to evaluate the efficacy and cost-effectiveness of an improved version of MobileMums (improvements detailed elsewhere [25]) as an intervention to increase the moderate-vigorous physical activity of Australian women with young children. The specific research questions (RQ) being addressed in this randomised controlled trial are:

- RQ1. Does an improved version of MobileMums result in increased levels of moderate-vigorous physical activity?
- RQ2. Is an improved version of MobileMums feasible to deliver and acceptable to participants?
- RQ3. Is MobileMums a cost-effective use of health resources?
- RQ4. What mediated the effect of MobileMums on moderate-vigorous physical activity?
- RQ5. What moderated the effect of MobileMums on moderate-vigorous physical activity?

The results from this trial will provide researchers and community stakeholders with a comprehensive evaluation of the impact of MobileMums and importantly, in the context of limited public health resources and the mediated intervention approach, the potential cost-effectiveness of translating this program into practice.

Methods

Study design

MobileMums is being evaluated in a 9-month, two-arm community-based randomised controlled trial. Participants are recruited on a rolling basis and randomly allocated to one of two study groups: the MobileMums intervention group or usual care control group. Data are collected before the program begins (T1), immediately post-intervention (T2, 3 months post baseline), and after a 6-month no contact maintenance period (T3, 9 months post baseline). The final T3 data were collected in December 2012, and the trial is ongoing with further qualitative assessment of program impact. The trial was designed and will be reported in accordance with the CONSORT guidelines for reporting randomised controlled

trials [28], and is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12611000481976). Ethical clearance for this research was obtained through the Queensland University of Technology Human Research Ethics Committee.

Setting

Women with young children were recruited from within a 30 kilometre radius of the Caboolture central business district. Caboolture is located 45 kilometres north of Brisbane, Australia, and had approximately 59,000 residents in 2011 [29]. Caboolture was chosen because it is socio-economically diverse and has a high proportion of women with young children compared with the rest of Australia [29]. This region was also chosen because our research team is involved in an ongoing maternal health partnership with local health service and community organisations. Therefore, if MobileMums is found to be cost-effective, the results from this trial can directly inform the translation of the program within this existing partnership.

Participant eligibility and recruitment

Women were recruited via one of three methods:

1) An existing database of women with young children who had participated in community surveys about infant and maternal health outcomes in 2006 and had consented to being re-contacted about future research. Each woman was mailed an invitation to participate, which was followed by a personalised text message and telephone call to determine their interest and eligibility.
2) Women were sent an invitation to participate via the Caboolture Early Years Centre Facebook© group. This message was not personally tailored but provided details of the study and asked women to contact research staff via telephone or email.
3) A second database of women with young children who had participated in a survey about maternal health in 2010 and consented to be contacted for further research were mailed an invitation to participate by the Queensland Centre for Mothers & Babies on behalf of the research team. We were not able to contact these women via text message or telephone, so were limited to those who contacted the research staff via telephone, email or reply paid letter in response to the mailed invitation.

Women's eligibility to participate was assessed via telephone interview. To be eligible, women must: have at least one child aged 5 years or younger; own a mobile telephone; not be pregnant at the time of consent (participants remained eligible if they fell pregnant during the 9-month trial); live within the designated residential area (defined above) and plan to live there for the next 12 months; and, be able to read and understand English. Any woman who had been advised not to exercise by her doctor was first required to receive their doctor's clearance before participating. Once eligibility was established, women provided informed verbal consent over the telephone.

Randomisation

In order to achieve similar groups, subjects were randomised in strata according to their baseline physical activity. Baseline physical activity was determined using T1 data from a single item physical activity assessment. The question asks participants to indicate (on a scale from 0–7 days) how many days per week (in the past 3-months) they "exercised for at least 30-minutes". This single-item question has acceptable criterion validity against Actigraph GT1M accelerometer data (r^s=0.38, $p<0.001$) for assessing days per week of at least 30-minutes of moderate-vigorous physical activity in women with young children. We used the data from this brief assessment for stratifying randomisation and not the more detailed T1 physical activity data as the brief assessment is more likely to be used by health agencies in the future to identify potential participants. Each participant was classified as either: not at all active (exercised 0 days per week); somewhat active (exercised between 1 and 4 days per week) or sufficiently active (exercised 5 days or more per week). Randomisation was managed by the project coordinator using lists created by the R software package using random permuted blocks of size ten.

MobileMums program

MobileMums was developed based on a five step iterative process involving a review of relevant literature and theory, and quantitative and qualitative formative research with the target group [25]. Each component of the MobileMums intervention operationalises at least one construct of the Social Cognitive Theory (self efficacy, goal setting skills, outcome expectancies, social support and perceived environmental opportunity) into a behaviour change technique [25].

Full details of the intervention development process and intricacies of each intervention component are beyond the scope of this manuscript and thus are provided elsewhere [25]. Briefly however, the MobileMums program begins with an initial face-to-face session with a trained MobileMums behavioural counsellor, at which the participants receive a MobileMums Participant Handbook, a MobileMums refrigerator magnet and information brochures, and details for accessing a dedicated MobileMums Facebook© group and a MobileMums website with a searchable, on-line exercise directory.

Thereafter, participants receive 12 weeks of tailored theory-based text messages and a follow-up telephone counselling session with their behavioural counsellor at 6 weeks (mid-intervention). Each participant is asked to identify a MobileMums support person. The consenting support person also receives 12 weeks of personalised, theory-based text messages encouraging them to offer instrumental, emotional, or informational support to their MobileMum.

Initial face-to-face counselling session

The aim of this session is to establish rapport between the participant and their MobileMums counsellor, to collect information to tailor the text messages content, identify a support person, and to initiate the behaviour change process. Participants are guided to: reflect on their previous physical activity patterns; identify expected outcomes of being active; set a SMART physical activity goal and reward for reaching their goal; identify barriers to reaching their goal and strategies to overcome them; and, to identify required support for reaching their goal and a specific person to be their MobileMums support person. To meet the needs of participants this session occurs at a time and location identified by the participant (e.g., their home) and lasts between 25 and 45 minutes.

MobileMums text messages

Participants receive 52 text messages over the 12-week program: five text messages per week for the first four weeks, and four text messages per week thereafter. Text messages include one 'goal check message' sent every Monday. The goal check message asks the participant to respond "yes" or "no" to a message asking whether she met her goal last week or not (e.g., *Jenny did u do all ur planned exercise last wk? Check ur planner magnet & text me back yes or no. Jacqui-MobileMums)*. Once she responds, she is sent a behaviourally-appropriate reply from her MobileMums counsellor (the goal check reply is in addition to the four or five text messages sent each week). Each text message is personalised using the participant's preferred name and signed off by their MobileMums counsellor's name. All text messages are tailored to at least one specific Social Cognitive Theory construct (see Table 1) and where appropriate also to the women's goal, her neighbourhood, her preferred reward or her expected outcomes for reaching her goal. In addition, where appropriate the text messages wording is tailored to the: participant's youngest child's name and the support person's name and gender. The text messages often referred women to other intervention resources such as the Facebook© group, website or handbook.

Table 1 Examples of how theoretical constructs are targeted by MobileMums text messages

Social cognitive theory construct	Example text message
Barrier self efficacy	Jenny take a minute 2 think about how much better u feel after an exercise session. Remember this next time u don't feel like doing it. Jacqui MobileMums
Outcome expectancy	Jenny. Don't feel guilty 4 taking time out 2 exercise, mums say they r more patient & understanding because they exercise. Jacqui MobileMums
Goal setting skills	Jenny, its OK 2 miss a day now & then, we all do. The trick is 2 get back in2 it ASAP. Review the strategies we planned in ur handbook. Jacqui MobileMums
Social support	Jenny. Remember Luke wants 2 support u. Make sure he knows what ur MobileMums goal is & what he can do 2 help u meet it. Jacqui MobileMums
Perceived environmental opportunity	Hi Jenny. MobileMums r enjoying aqua aerobics at Redcliffe Aquatic Centre. Tues & Thurs 4 pm. Costs $6.50. Childcare available. Jacqui MobileMums

Support person text messages

The support person is sent three text messages per week. Every second week one of these text messages is tailored to how or whether their MobileMum participant responded to their weekly goal check (e.g., *Luke, congratulate Jenny. She met her goal last wk. Can u help make time 4 her reward? Its a bubble bath. Jacqui-MobileMums*).

Week 6 telephone counselling session

During Week 6 participants receive a telephone counselling call from their MobileMums counsellor. The aim of this follow-up session is to update the participant's exercise goals and strategies in order to refine the tailoring content of the text messages sent in Weeks 7–12.

Other resources

Throughout the program participants have ongoing access to their MobileMums Participant Handbook, MobileMums website with searchable, on-line exercise directory, MobileMums Facebook© group, MobileMums refrigerator magnet, and the state-of-the-art information brochures, all of which they receive at the initial face-to-face consult.

Usual care control group

Women in the control group receive brief written feedback on their physical activity levels (based on accelerometer data) following each assessment. At baseline, they also receive standard print materials that encourage physical activity. They do not receive any contact with the behavioural counsellor, but do have access to the MobileMums website and a separate, non-moderated Facebook© group that only control participants can

access. The treatment of this study group was meant to reflect the standard minimal care that our partner organisations could feasibly deliver without specific funding (e.g., standard print materials and non-moderated Facebook© access), with the exception of accelerometer feedback, which was included to increase participant compliance with assessment procedures and reduce study attrition.

Data collection procedures

Data are being collected via objective activity monitors (accelerometers), self-administered questionnaire and telephone interview. At each data collection point, participants are sent an assessment package via registered Express Post that contains: an introductory letter; an accelerometer; an accelerometer wear-time logbook; a reply paid registered Express Post mailbag; a self-complete questionnaire; and, an instruction/reference sheet for use during the telephone interview. Two days after the assessment package is sent, the participant is telephoned by research staff to determine if the package has arrived and: 1) provide verbal instruction on how to wear the accelerometer and complete the accelerometer wear-time logbook and questionnaire; and, 2) schedule a time to complete the telephone interview. Three days after the agreed start date for wearing the accelerometer a courtesy phone call is made to ensure correct wear time and placement. A third phone call is made on the expected seventh wear day to prompt efficient return of the accelerometer in the reply paid mailbag. If convenient for the participant, the telephone interview is completed during one of the accelerometer check-in calls; otherwise a separate time convenient to the woman is arranged.

The same data collection procedures are used at both follow-up assessments; however, superfluous socio-demographic variables collected at baseline were removed, and replaced with items to assess participant's recall, use and satisfaction with the program. All participants receive a nominal gratuity ($20 gift voucher) for each completed assessment to recognise their contribution to the research.

Primary outcome

The primary outcome is change in moderate-vigorous physical activity (RQ 1). This outcome is being assessed objectively by accelerometer and subjectively through a telephone-administered questionnaire. The accelerometer provides an objective estimate of total accumulated moderate-vigorous physical activity, whereas the self-report questionnaire assesses specific types of moderate-vigorous activity (e.g., brisk walking for exercise). It was important for us to include this self-reported measure of women's activity, since most women in the pilot study chose to set a SMART exercise goal specific to brisk walking [27], and the accelerometers cannot isolate walking from other moderate intensity activity. Also, MobileMums targets increases in structured, leisure-time physical activity, and the self-report measure allows us to examine activity reported within this domain, while the accelerometer does not differentiate between activity domains.

Accelerometer

Total accumulated moderate-vigorous physical activity is being assessed using data from Actigraph GT1M accelerometers (Actigraph, LLC, Fort Walton Beach, Florida). Each accelerometer is about the size and shape of a matchbox and is worn on an elastic belt around the waist. It collects data that can be extrapolated into time spent being active (minutes/week) at different intensity levels. Participants are asked to wear it for all waking hours (minimum 10 hours per day) for seven consecutive days, removing it only for sleep or water-based activities. They are asked to record each time they put the accelerometer on or off, as well as any non-wear activities (e.g. water-based activities) in their accelerometer wear-time logbook. The logbook included detailed instructions (with photographs) of how to wear the accelerometer. The accelerometer is set to record data in 1-minute epochs, which will provide output in counts per minute (cpm). Based on a combination of the wear-time logs and the accelerometer data, invalid days of observation (days with < 10 hours wear or excessive counts ≥ 20,000 cpm) will be discarded. Moderate-intensity activity (1952 to 5724 cpm), and vigorous-intensity activity (≥ 5725 cpm) time will be calculated based on standardised cut-points [30]. Data will be reported as averages for valid days and will be summarised to indicate minutes per week of moderate-vigorous activity. The data collection and analytic protocol proposed for this data comply with the best-practice guidelines for conducting accelerometer-based activity assessments in field-based research [31].

Questionnaire

The Australian Women's Activity Survey (AWAS) is administered during the telephone interview and was developed to specifically assess physical activity among women with young children [32]. The AWAS assesses women's typical weekly activity in the past month across five domains (planned, transport, childcare, domestic and work-related) and three intensity levels (light, moderate and vigorous). The interview-administered AWAS has good test-retest reliability (ICC=0.80 (0.65–0.89)) and acceptable criterion validity (compared to accelerometer data; r^s=0.28, p=0.01) for measuring planned weekly physical activity among women with young children [32]. The key variables that will be extracted from the AWAS are: minutes per week of Planned Moderate-

Vigorous Physical Activity; and, minutes per week of Brisk Walking for Exercise. The research staff administering the AWAS received training and conducted role plays before collecting participant data. Throughout the trial, research staff record (with participant consent) two telephone interviews on three separate occasions. A study investigator (BF) listens to these recordings and provides feedback on the AWAS administration in an attempt to increase script fidelity and reduce inter-interviewer variability.

Secondary outcomes

Secondary outcomes are: program feasibility and participant reports of program acceptability (RQ2); cost-effectiveness (RQ3); potential mediators (RQ4); and, moderators (RQ5).

Program feasibility

Intervention implementation data are assessed through either participant's self-report in the paper questionnaire (i.e., treatment of text messages, use of MobileMums refrigerator magnet) or through objective tracking of delivery data (i.e., duration of initial counselling session, number of text messages sent/received, number of goal check text message responses received, number of Facebook© posts, and website usage).

Program acceptability

Participants' recall of, use and satisfaction with the program are assessed using self-report items used previously by the investigators [10,27]. Participant responses to the goal check text messages, any unprompted text messages sent by participants, and any additional communication with the behavioural counsellor was monitored [27]. Participants are also asked to describe the MobileMums program in one sentence to provide an unfettered qualitative assessment of the program.

Cost-effectiveness

Participant-reported use of health care services is assessed in the telephone interview at each data collection point. Participants were asked if they have had any consultations for: their own health with various health professionals; any visits to accident and emergency department; visits by home health nurses; hospital admissions (plus length of stay); and, any other costs associated with taking up any form of physical activity. Costs associated with any reported health service use will be estimated from the Commonwealth Government schedule of re-imbursements [33]. Additional costs associated with program delivery (e.g., computer/database, print materials, text messages, behavioural counsellor time, and other staff costs) were monitored by research staff. Health benefits are collected in the self-administered paper questionnaire at each data collection point using the SF-12v2™ Health Survey [34]. The SF-12 data will be converted to SF-6D utility scores using an established algorithm [35,36]. The SF-6D provides a preference-based value of health benefits derived from standard questions, and a valid estimate of Quality Adjusted Life Years (QALYs) [37]. Change in QALYs will be used as an estimate of health benefit. In line with current theory and recommendations, participant-based production losses will not be included on the cost side of the analysis but (implicitly) counted within the QALY estimation [37,38].

Theoretical mediators

The MobileMums program is grounded in Social Cognitive Theory and the intervention strategies target change in the specific theoretical constructs proposed [25], therefore the following five constructs are being evaluated as potential mediators via the self-administered questionnaire at each data collection point. *Physical activity barrier self efficacy* is assessed on a 5-point Likert scale (from 1 'not at all confident' to 5 'very confident'), using a 12-item tool adapted from a previous scale [39]. Our version includes two additional items for postnatal women (i.e., I could exercise even when: 'I don't have anyone to look after the kids'; 'I have housework to do'). This adapted version of the scale has demonstrated sensitivity to change among postnatal women [10,26] and had acceptable internal consistency (Cronbachs $\alpha = 0.71$) [26]. *Outcome Expectancy* is measured using 10-item scale developed by Rodgers & Brawley [40]. Participants rate outcome likelihood (on a 10-point scale, 0–100% likelihood) and outcome value (on a 9-point scale, 1–9 importance) for seven physical activity outcomes and ratings are multiplied to indicate overall outcome expectancy (range 0–900). Consistent with the creator's recommendations, the specific physical activity outcomes used in this study were determined from formative research with the target population. The most commonly reported positive (weight loss, improved fitness, more energy, less stress, improved mental well-being) and negative outcomes (injury, lose time to do other things) were included. Negative outcome expectancies were included because expectations are thought to be better predicted when both positive and negative outcomes are considered [41]. Our previous trial [26] and others [42] have demonstrated that the measure was sensitive to change in a physical activity intervention among postnatal women. The scale has acceptable internal consistency (Cronbachs $\alpha = 0.72$) [26]. *Goal Setting Skills* are measured using the 10-item Exercise Goal-setting Scale (EGS)[43]. This scale has good test retest reliability ($r = 0.87$) over an 8-week period [43]. The EGS items assesses setting goals (e.g., I often set exercise goals), self-monitoring (e.g., I usually keep track of my progress in meeting my goals) and problem solving (e.g., If I do not

reach my goals, I analyse what went wrong). Each item is measured on a 5-point Likert scale, but following our formative research with 12 postnatal women the original anchors ('does not describe' to 'describes completely') were found to be difficult to interpret so we adapted the EGS anchors to 1 'strongly disagree' to 5 'strongly agree'. The adapted version of EGS had good internal consistency (Cronbachs α = 0.84) [26], similar to that of the original scale (r = 0.89)[43]. *Physical activity social support* from the participant's partner (husband or defacto) and from their family or friends is assessed on a 5-point Likert scale using the Social Support for Exercise Scale [44]. Five items, including an additional one ('offered to mind the kids so I could be more physically active') are assessed on a scale from 1 'never' to 5 'very often'. The original scale has good test-retest reliability (r = 0.55–0.79)[44], and this slightly modified version has demonstrated good internal consistency (Cronbachs α = 0.90) [26] and sensitivity to change among women with young children [10,26]. At T2 and T3 we included five additional items to specifically assess the support that participants received from their nominated MobileMums support person. *Perceived Environmental Opportunity for Exercise:* was measured using 12 items designed and implemented by Hoehner and colleagues [45]. These items were derived from a review of three commonly used questionnaires to assess environmental impact on physical activity participation [46], and are assessed on a five point Likert scale from 1 'strongly disagree' to 5 'strongly agree'. Based on our formative research we added two additional items to the scale ('There are footpaths wide enough to fit prams in my neighbourhood'; 'Unattended dogs make it unsafe to walk in my neighbourhood'). The adapted scale has an acceptable internal consistency (Cronbachs α = 0.75) [26].

Moderators

Demographic (e.g., age, number of children, employment status, education) and health-related (SF12v2™ Health Survey) [34] moderators were assessed in the self-administered questionnaire. Demographic questions follow the same format and response options used in the Census by the Australian Bureau of Statistics [47] to aid interpretation of representativeness of the sample.

Sample size

Our sample size was based on the clinically meaningful increase in physical activity (assessed by the AWAS) observed in our pilot study (40 minutes/week) [27]. We chose to base the sample size on self-report physical activity data, not the objective accelerometer data, because our pilot data suggested the AWAS was likely to produce the higher sample size estimate due to larger variance. Using the variance observed in the self-report data of 102 minutes/week [27], and assuming 80% power and two-sided significance of 5% we needed 102 women per group. Estimating a 25% dropout, this figure was inflated to 128 per group, or 256 total.

Data analyses

Data analyses will follow intention-to-treat principles [28], so all participants will be analysed according to their randomised group regardless of whether they complied with the program or not. Missing physical activity data will be imputed using a model that accounts for the often skewed distribution of physical activity. Missing data will be imputed using a regression model based on time and a subject's previous responses using a random intercept. To account for the uncertainty in imputing missing data the analyses will use multiple imputation using the WinBUGS software. Statistical significance will be set to 5% and 95% confidence intervals will be given for all results.

Changes in physical activity

Changes in accelerometer-measured moderate-vigorous physical activity (minutes/week) and in AWAS planned moderate-vigorous physical activity and brisk walking (minutes/week) will be analysed using repeated-measures models. Preliminary descriptive analyses will consider the longitudinal trajectories of participants to determine the homogeneity of trajectories and identify outliers. We will fit the repeated measures models using a generalised estimating equations framework. Estimates of the main effects of time by intervention will be used to assess the impact of intervention on each outcome. Possible attrition bias will be assessed using a longitudinal model with a binary dependent variable of dropout at each assessment time. This model will include time-independent covariates such as age, and time-dependent covariates such as previous physical activity.

Cost-effectiveness analysis

Costs and QALYs will be modelled using a decision analytic Markov model [37], with due consideration of parameter uncertainty as described by probabilistic sensitivity analysis. One thousand random samples will be drawn from probability distributions and cost-effectiveness acceptability curves plotted for the two study groups to reveal the probability the program is cost-effective. This method has been used in previous cost-effectiveness studies [37,48,49].

Mediator analysis

Potential mediation will be explored using a simple product-of-coefficient approach using Sobel tests [50]. This test will examine whether the 'indirect effect' (or the 'mediated effect') of the MobileMums intervention is significantly different from zero [50]. The indirect effect

is the difference between the 'total effect' of the intervention on physical activity and the 'direct effect' of the intervention on physical activity after controlling for proposed mediators (Social Cognitive Theory constructs). It should be acknowledged that this trial was not powered to detect mediation and this will be an exploratory analysis.

Moderator analysis

Exploratory analysis of potential moderators will determine whether intervention effects differ across demographic (e.g., age, gender) and health-related (e.g., BMI, SF-12) characteristics. This analysis will be performed by considering the statistical significance of an interaction between a potential moderator and the intervention as part of the generalised estimating equations model.

Discussion

This paper describes the methods for evaluating the improved version of the MobileMums program in a large scale community-based randomised controlled trial. The results of this trial will address multiple indicators of program evaluation including efficacy, feasibility, acceptability, cost-effectiveness, mediation and moderation. The results will advance both the science and practice of physical activity interventions for women with young children.

The evidence base for physical activity interventions among women with young children is only starting to include evaluation of mediated (non face-to-face) mechanisms of program delivery [23,24], this is despite the need for highly accessible, flexible program delivery in this population with high caregiving demands. This trial will be the first (other than our pilot evaluation of MobileMums [27]) to evaluate a text message-delivered physical activity intervention for women with young children, and one of the first to evaluate a program delivered primarily by a mediated mechanism for this target group. Results of this trial will also contribute to the evidence for the application of Social Cognitive Theory in interventions to change physical activity and the relative contributions of the theoretical constructs as mediators of change.

Importantly, this trial will provide more valid evidence of the impact of MobileMums on overall physical activity by using objective physical activity measures from an adequately powered sample and assessing maintenance of behaviour change beyond the period of direct program delivery. Assessing the maintenance of behaviour change following an intervention is not common in physical activity trials in general [51] and is very rare within the evidence targeting women with young children. Another strength of this trial is the evaluation of cost-effectiveness of the MobileMums program. Cost reduction for program delivery is one of the key drivers for text message-delivered programs, but there is limited cost-effectiveness evidence to support this rationale.

This thorough evaluation will inform whether further translation of the MobileMums program beyond researcher-administration into community-based practice is warranted. The study investigators are conducting this trial within the context of an existing research-health delivery partnership and thus have the potential to rapidly facilitate the research findings into practice within the target community. We anticipate the findings of this trial will have impact on the practice of physical activity promotion for women with young children within our partnership region. Collectively, the evidence generated by this trial can inform physical activity promotion efforts for women with young children and other populations with accessibility to text messaging interventions, and advance the broader literature for physical activity behaviour change, application of Social Cognitive Theory, and delivery of health behaviour change programs via text messaging.

Abbreviations

AWAS: Australian women's activity survey; RQ: Research question.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

AM conceived the study, led the design of the study, measurement and intervention, coordinated all aspects of study implementation and drafted the manuscript. YM participated in study conception, design and measurement, recruitment of participants, and drafting the manuscript. NG participated in design of the study, measurement, and cost effectiveness analysis and in drafting the manuscript. AB participated in design of the study, measurement and statistical analyses, conducted the randomisation of participants and participated in drafting the manuscript. BF participated in study conception, recruitment, design and measurement, development of the intervention and drafting of the manuscript, and coordinated the intervention delivery. All authors read and approved the final manuscript.

Acknowledgements

We wish to thank the women who participated in the study. We would also like to thank project staff for their integrity and commitment, Jasmine O'Brien, Sarah Mair, Jacqueline Watts, Joy Nicols and Kylie Heenan. Thanks also to the Queensland Centre for Mothers & Babies at The University of Queensland who assisted us by inviting women on their research database to participate in this trial. This study was supported by a National Health and Medical Research Council (NHMRC) project grant # 614244. A Marshall is supported by a NHMRC Career Development Award #553000.

Author details

[1]Queensland University of Technology, Institute of Health and Biomedical Innovation, School of Public Health and Social Work, Faculty of Health, Brisbane, Australia. [2]The University of Queensland, School of Psychology, Brisbane, Australia. [3]The University of Queensland, School of Population Health, Cancer Prevention Research Centre, Brisbane, Australia.

Received: 5 April 2013 Accepted: 13 June 2013
Published: 19 June 2013

References

1. Haskell WL, Lee IM, Pate RR, Powell KE, Blair SN, Franklin BA, Macera CA, Heath GW, Thompson PD, Bauman A: **Physical activity and public health: updated recommendation for adults from the american college of sports**

medicine and the american heart association. *Medicine and Science in Sports and Exercise* 2007, **39**(8):1423 1434.
2. Centers for Disease Control and Prevention: **Prevalence of physical activity, including lifestyle activities among adults United States, 2000 2001.** *Morb Mortal Wkly Rep* 2003, **52**(32):764 769.
3. Craig R, Mindell J, Hirani V: *Health survey for england 2008: physical activity and fitness. Volume 1.* London: The NHS Information Centre for health and social care; 2009:395.
4. Australian Institute of Health and Welfare: *Key indicators of progress for chronic disease and associated determinants: data report. Cat. no. PHE 142.* Canberra: AIHW; 2011.
5. Brown W, Mishra G, Lee C, Bauman A: **Leisure time physical activity in aAustralian women: relationship with well being and symptoms.** *Res Q Exerc Sport* 2000, **71**(3):206 216.
6. Brown W, Trost S: **Life transitions and changing physical activity patterns in young women.** *American Journal of Preventitive Medicine* 2003, **25**(2):140 143.
7. Brown WJ, Burton NW, Rowan PJ: **Updating evidence on physical activity and health in women.** *Am J Prev Med* 2007, **33**(5):404 411.
8. Nomaguchi KM, Bianchi SM: **Exercise time: gender differences in the effects of marriage, parenthood, and employment.** *J Marriage Fam* 2004, **66**(2):413 430.
9. Collins BS, Marshall AL, Miller YD: **Physical activity in women with young children: How can we assess "anything that's not sitting"?** *Women Health* 2007, **45**(2):95 116.
10. Miller Y, Trost S, Brown W: **Mediators of physical activity behavior change among women with young children.** *American Journal of Preventitive Medicine* 2002, **23**(2):98 103.
11. Lewis B, Ridge D: **Mothers reframing physical activity: family oriented politicism, transgression and contested expertise in Australia.** *Soc Sci Med* 2005, **60:**2295 2306.
12. Miller Y, Brown W: **Determinants of active leisure for women with young children an "ethic of care" prevails.** *Leisure Sciences* 2005, **27:**405 420.
13. Clarke KK, Freeland Graves J, Klohe Lehman DM, Milani T, Nuss H, Laffrey S: **Promotion of physical actvity in low income mothers using pedometers.** *J Am Diet Assoc* 2007, **107:**962 967.
14. Cody R, Lee C: **Development and evaluation of a pilot program to promote exercise among mothers of preschool children.** *Int J Behav Med* 1999, **6**(1):13 29.
15. Cramp A, Brawley L: **Moms in motion: a group mediated cognitive behavioural physical activity intervention.** *Int J Behav Nutr Phys Act* 2006, **3**(23):1 9.
16. Fahrenwald NL, Atwood JR, Walker SN, Johnson DR, Berg K: **A randomized pilot test of "Moms on the Move" a physical activity intervention for WIC Mothers.** *Ann Behav Med* 2004, **27**(2):82 90.
17. Watson N, Milat AJ, Thomas M, Currie J: **The feasibility and effectiveness of pram walking groups for postpartum women in western Sydney.** *Health Promot J Aust* 2005, **16**(2):93 99.
18. Armstrong K, Edwards H: **The effectiveness of a pram walking exercise programme in reducing depressive symptomatology for postnatal women.** *Int J Nurs Pract* 2004, **10:**177 194.
19. Daley AJ, Winter H, Grimmett C, McGuinness M, McManus R, MacArthur C: **Feasibility of an exercise intervention for women with postnatal depression: a pilot randomised controlled trial.** *Br J Gen Pract* 2008, **58**(548):178 183.
20. Armstrong K, Edwards H: **The effects of exercise and social support on mothers reporting depressive symptoms: a pilot randomized controlled trial.** *Int J Ment Health Nurs* 2003, **12:**130 138.
21. Currie J: **Pramwalking as postnatal exercise and support: an evaluation of the stroll Your Way to Well Being Program and supporting resources in terms of individual participation rates and community group formation.** *Australian College of Midwives* 2001, **14**(2):21 25.
22. Rowley C, Dixon L, Palk R: **Promoting physical activity: walking programmes for mothers and children.** *Community Pract* 2007, **80**(3):28 32.
23. Albright CL, Maddock JE, Nigg CR: **Increasing physical activity in postpartum multiethnic women in Hawaii: results from a pilot study.** *BMC Womens Health* 2009, **9:**4.
24. Reinhardt JA, van der Ploeg HP, Grzegrzulka R, Timperley JG: **Implementing lifestyle change through phone based motivational interviewing in rural based women with previous gestational diabetes mellitus.** *Health Promot J Austr* 2012, **23**(1):5 9.
25. Fjeldsoe BS, Miller YD, O'Brien JL, Marshall AL: **Iterative development of MobileMums: a physical activity intervention for women with young children.** *Int J Behav Nutr Phys Act* 2012, **9:**151.
26. Fjeldsoe BS, Miller YD, Marshall AL: **Social cognitive mediators of the effect of the MobileMums intervention on physical activity.** *Health Psychol* 2012, **2012:**2012.
27. Fjeldsoe BS, Miller YD, Marshall AL: **MobileMums: a randomized controlled trial of an SMS based physical activity intervention.** *Ann Behav Med* 2010, **39**(2):101 111.
28. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, *et al*: **Improving the quality of reporting of randomized controlled trials. The CONSORT statement.** *JAMA* 1996, **276**(8):637 639.
29. Australian Bureau of Statistics: *2011 Census of population and housing: Basic community profile, Caboolture. Cat no. 2001*; 2011.
30. Freedson P, Melanson E, Sirard J: **Calibration of the Computer Science and Applications Inc. accelerometer.** *Medicine and Science in Sports and Exercise* 1998, **30**(5):777 781.
31. Matthews CE, Hagstromer M, Pober DM, Bowles HR: **Best practices for using physical activity monitors in population based research.** *Med Sci Sports Exerc* 2012, **44**(1 Suppl 1):S68 S76.
32. Fjeldsoe BS, Marshall AL, Miller YD: **Measurement properties of the Australian women's activity survey.** *Med Sci Sports Exerc* 2009, **41**(5):1020 1033.
33. Australian Government: In *Medicare benefits schedule book.* Edited by Department of Health and Ageing. Canberra, Australia: Australian Government Department of Health and Ageing; 2012.
34. Ware J Jr, Kosinski M, Keller SD: **A 12 item short form health survey: construction of scales and preliminary tests of reliability and validity.** *Med Care* 1996, **34**(3):220 233.
35. Brazier J, Roberts J, Deverill M: **The estimation of a preference based measure of health from the SF 36.** *J Health Econ* 2002, **21**(2):271 292.
36. Brazier J, Usherwood T, Harper R, Thomas K: **Deriving a preference based single index from the UK SF 36 Health Survey.** *J Clin Epidemiol* 1998, **51**(11):1115 1128.
37. Graves N, McKinnon L, Reeves M, Scuffham P, Gordon L, Eakin E: **Cost effectiveness analyses and modelling the lifetime costs and benefits of health behaviour interventions.** *Chronic Illn* 2006, **2**(2):97 107.
38. Gordon L, Graves N, Hawkes A, Eakin E: **A review of the cost effectiveness of face to face behavioural interventions for smoking, physical activity, diet and alcohol.** *Chronic Illn* 2007, **3**(2):101 129.
39. Marcus BH, Owen N: **Motivational readiness, self efficacy and decision making for exercise.** *J Appl Soc Psychol* 1992, **22**(1):3 16.
40. Rodgers WM, Brawley LR: **The role of outcome expectancies in participation motivation.** *J Sport Exerc Psychol* 1991, **13:**411 427.
41. Williams DM, Anderson ES, Winett RA: **A review of the outcome expectancy construct in physical activity research.** *Ann Behav Med* 2005, **29**(1):70 79.
42. Cramp A, Brawley L: **Sustaining self regulatory efficacy and psychological outcome expectations for postnatal exercise: effects of a group mediated cognitive behavioural intervention.** *Br J Health Psychol* 2009, **14**(Pt 3):595 611.
43. Rovniak LS, Anderson ES, Winnett RA, Stephenson RS: **Social cognitive determinants of physical activity in young adults: a prospective structual equation analysis.** *Ann Behav Med* 2002, **24**(2):149 156.
44. Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR: **The development of scales to measure social support for diet and exercise behaviors.** *Prev Med* 1987, **16:**825 836.
45. Hoehner CM, Brennan LK, Elliot MB, Handy SL, Brownson RC: **Perceived and objective environmental measures and physical actvity among US adults.** *Am J Health Promot* 2005, **28**(2):s105 s116.
46. Brownson RC, Chang JJ, Ainsworth BE, Kirtland KA, Saelens BE, Sallis JF: **Measuring the environment for friendliness toward physical activity: a comparison of the reliabililty of 3 questionnaires.** *Am J Public Health* 2004, **94**(3):473 483.
47. Statistics ABo: *Census dictionary, 2006 (reissue).* ABS, Canberra, ACT: Cat no. 2901.0; 2006.
48. Graves N, Barnett AG, Halton KA, Veerman JL, Winkler E, Owen N, Reeves MM, Marshall A, Eakin E: **Cost effectiveness of a telephone delivered intervention for physical activity and diet.** *PLoS One* 2009, **4**(9):e7135.
49. Eakin EG, Reeves MM, Marshall AL, Dunstan DW, Graves N, Healy GN, Bleier J, Barnett AG, O'Moore Sullivan T, Russell A, *et al*: **Living well with diabetes:**

a randomized controlled trial of a telephone delivered intervention for maintenance of weight loss, physical activity and glycaemic control in adults with type 2 diabetes. *BMC Public Health* 2010, 10(1):452.

50. Preacher KJ, Hayes AF: SPSS and SAS procedures for estimating indirect effects in simple mediation models. *Behav Res Methods Instrum Comput* 2004, 36(4):717 731.
51. Fjeldsoe BS, Neuhaus M, Winkler E, Eakin E: Systematic review of maintenance of behavior change following physical activity and dietary interventions. *Health Psychol* 2011, 30(1):99 109.

doi:10.1186/1471 2458 13 593
Cite this article as: Marshall *et al.*: Moving MobileMums forward: protocol for a larger randomized controlled trial of an improved physical activity program for women with young children. *BMC Public Health* 2013 13:593.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit

BioMed Central