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Effect of a multicomponent intervention in postnatal mothers' groups on meeting the Australian Physical Activity Guidelines for infants: protocol for a randomised controlled trial

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ABSTRACT

Introduction Given the importance of tummy time and the low levels of tummy time reported globally, there is a need for high-quality intervention strategies to promote tummy time. This study describes the protocol of a randomised controlled trial that aims to determine the effectiveness of a multicomponent intervention delivered in postnatal mothers' groups in increasing infant tummy time.

Methods and analysis A randomised controlled trial will be conducted. Eligible participants will be mothers and their infants attending postnatal mothers' groups (New South Wales, Australia). Participants will be randomised to participate in either (1) infant tummy time intervention group (practice, education, WhatsApp) plus usual care; or (2) usual care group. Randomisation process and outcome assessors will be blinded. The intervention will comprise an online education and practice session (60 min) and 4 weeks of WhatsApp messaging (standardised, three times per week). Usual care will be attendance at a mothers group once per week for 3 weeks for information and support for ad hoc mother craft activities (standard practice provided by early childhood nurses for this local health district). The primary outcome will be the amount of infant tummy time using the GENEActiv accelerometer and a questionnaire (post intervention). The accelerometer will be worn on the right hip secured by an elastic belt around the waist. Wear and non-wear time will be classified using temperature and z-axis cut points as per previous research. This protocol paper presents the scientific background and proposed methods of the randomised controlled trial. Findings will inform the design of practically based strategies to inform clinicians, educators and parents about infant physical activity.

Ethics and dissemination The University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee approved the study (2020/ETH02970). Dissemination plan is publication, staff training and conference presentations.

Trial registration number Australian New Zealand Clinical Trials Registry ACTRN12621000575831; Pre-results.

Strengths and limitations of this study

- ► The use of a process (mothers' groups) already in place in existing health districts (strength).
- ► Use of the online delivery platform and mobile phone application enhances the potential for the scale up of the intervention to other areas (strength).
- ► Accelerometer may be too burdensome for new mothers (limitation), as such tummy time will also be assessed using a questionnaire.

INTRODUCTION

Physical activity in early childhood is important for healthy growth and initiates a lifetime of healthy behaviours.[1] The promotion of physical activity starts in the infant stage of life, for infants who are not yet walking or mobile, as playing on their tummy ('tummy time'). The research investigating the benefits of tummy time reports improved motor development[2–8] and the reduced likelihood of head shape abnormalities.[9–12] Based on the evidence regarding the connection between tummy time and motor development, in 2019, the WHO published the first global guidelines on physical activity for children under the age of 5, including infants. The WHO guidelines recommend tummy time for at least 30 min spread throughout the day while awake and in a supervised environment.[1]

Despite the strong support for the importance of tummy time, prevalence rates are poor. Gross *et al* reported that among 456 3-month-old infants, only 32% had practiced tummy time on the floor.[13] This finding was similar to baseline data (N=445) from the Melbourne Infant Feeding, Activity and Nutrition Trial Program.[14] They reported the prevalence of infants meeting the guidelines for physical activity (30 min of tummy time per day) was 29.7%.

Due to the association of tummy time with improved health outcomes and the low rates of adherence to the guidelines, an

intervention designed to improve tummy time practices is required. Previous studies have demonstrated positive effects of parent education programmes on tummy time practices.[15 16] Further work using objective measurement and complementary strategies would be beneficial to continue making progress in this area. Bandura's Social Cognitive Theory is a framework which considers the influence of personal, behavioural and environmental factors on action.[17] As such, this theory could be used to influence the amount of tummy time that is provided to an infant. For example, personal factors (ie, is tummy time important?) could be addressed by an education session; behavioural factors (ie, including tummy time as part of their daily activities) could be addressed by determining individual strategies to set aside time for tummy time and providing regular encouragement or reminders to participate in tummy time; lastly, environmental factors (ie, having a safe space and equipment to assist tummy time) could be addressed by practising tummy time with other mothers and discussing techniques, strategies and equipment to achieve tummy time consistent with the guidelines.

Based on Bandura's Social Cognitive Theory,[17] a pilot cluster randomised controlled trial (RCT) targeting parents of infants was designed and conducted (N=35).[18] This pilot RCT included a group tummy time session, the use of WhatsApp social media and accelerometers (GENEActiv) to objectively measure the amount of tummy time the infant received. The pilot study showed that the intervention was feasible and well received by participants. Specifically, (1) recruitment, retention and collection of objective data met feasibility targets; (2) acceptability was met with intervention mothers reporting the information, goal planning and handouts significantly more useful and relevant than control group mothers ($p<0.01$) and (3) moderate effect sizes favouring the intervention group were found at post intervention for tummy time duration, adherence to physical activity guidelines and infant ability in prone and supine. Intervention infants had a mean of 30.3 min and 30% adherence to guidelines (95% CI 0 to 60.6 min) compared with control infants (mean=16.6 min and 13% adherence to guidelines (95% CI 0 to 42.1 min, Cohen's d=0.5). The small sample size and homogenous (middle income, highly educated) participants were limitations of this study. In addition, as a face-to-face method of interaction was used, groups of mothers were randomised to receive either the intervention or usual care. A study using individual randomisation, with a larger, more diverse sample size and an online method of intervention delivery will enable this programme to be appropriately assessed and then potentially disseminated to other areas if successful.

Our pilot RCT[18] was the first known study to integrate this intervention into existing health service mothers' groups (which also did not require many resources to support). In addition, the improvement in healthy behaviours has also been demonstrated by interventions that have been delivered to parents by text messaging or online programs.[19] This proposed full-scale RCT will further investigate this intervention to establish the effectiveness of practically based strategies to inform clinicians, educators and parents about infant physical activity in a real-world setting. The aim of this study is to determine the effectiveness of a multicomponent intervention incorporating WhatsApp and an online tummy time class in postnatal mothers' groups, on infant physical activity levels (operationalised as tummy time).

METHODS AND ANALYSIS

This paper presents the protocol of an RCT to determine the effectiveness of a multicomponent intervention delivered in postnatal mother's groups on infant tummy time.

Ethical considerations

The University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee approved the study (2020/ETH02970). This trial was prospectively registered in May 2021 with the Australian New Zealand Clinical Trials Registry (ANZCTR). Written informed consent will be obtained by the infant's mother on behalf of themselves and the infant prior to the commencement of the study.

Participants and recruitment

Mothers who plan to attend with their baby to their Local Health District (New South Wales, Australia) mothers' group will be recruited by the investigators of this study. Mothers who have had a healthy baby (ie, no functional deficits) who is not yet sitting will be included in the study. Recruitment will occur at the first mothers' group session which is usually run by the health service using an online platform (recruitment start date, 8 June 2021). The investigators of the study will be allocated 10 min to explain the study and leave their contact details for those who may be interested. This method will ensure there is no coercion from a possible unequal relationship between treating health professional (Early Childhood Nurse) and the participant. Figure 1 outlines the flow of the study according to the Consolidated Standards of Reporting Trials (CONSORT) flow diagram (http://www.consort-statement.org/). Figure 2 outlines the schedule of enrolment, usual care, intervention and assessments.

Usual care

It is usual practice for the Early Childhood Nurses in this health district to group mothers together in the postnatal stage and invite them to come together weekly for support and education regarding infant care. These groups typically discuss topics such as feeding, settling, tummy time and development on an ad hoc basis. A similar comparison group was used in the pilot RCT and was feasible and acceptable.[18] Due to COVID-19, the face-to-face sessions have been modified to ensure patient safety and to reduce the risk of transmission.[20] These sessions now consist of

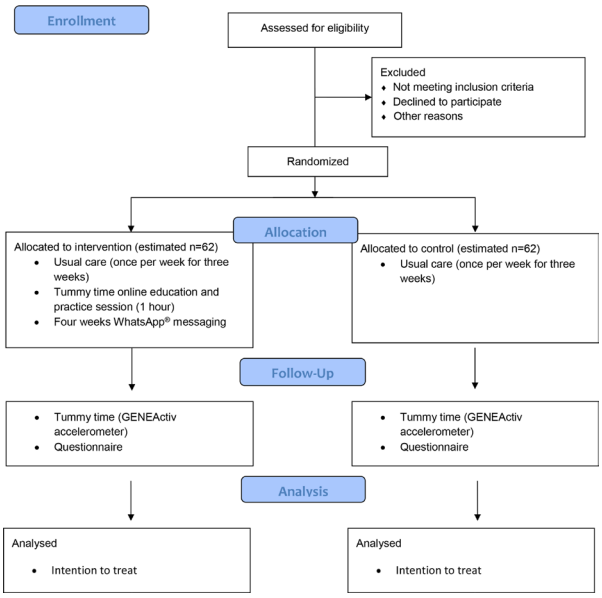

Figure 1 Consolidated Standards of Reporting Trials flow diagram.

one online session and two outdoor walking groups. It is conducted once per week over 3 weeks.

Intervention

The intervention is based on Bandura's Social Cognitive Theory[17] to enhance behaviour change (attention, retention, production, motivation). This intervention will address these processes by: (1) providing educational resources and practice sessions to engage the attention of the mothers (attention); (2) matching participant skill and education level to the content (retention); (3) including incentives that are application and important to the audience (production); and (4) emphasising choice, control, challenge, curiosity and mastery (motivation). The intervention will consist of usual care plus the addition of a tummy time group exercise class and education session. The intervention is a 1-hour session to be delivered via an online platform (with camera) and then 4 weeks of standardised group WhatsApp messaging. WhatsApp will be used to motivate, remind and provide a platform to enable mothers to share personal experiences about tummy time with their mother's group. The investigator will send three standardised messages per week and mothers will be asked to upload a photo or message about the tummy time session they conducted with their baby (eg, (Baby name) managed 4 min today!). Standardised replies will be sent to the group after a mother posts a message about their baby's tummy time (eg, Yay! Well done (baby name)!). No reply will be sent if the mother's message is not related to tummy time. An individual message will only be sent if the mother requests a referral or requires help with the care of their baby, all requests will be forwarded to their early childhood nurse. The education and practice session (online) will start with beginner level tummy time exercises (prone on a parent's chest, being held in prone) and then shown how to gradually upgrade to advanced level tummy time exercises (playing on the floor on their tummy) for increased periods of time. Parents can choose which position to start their baby's tummy time and they can start on the floor if they would like to. Parents will be informally educated about the benefits of tummy time, positions, setting aside time and equipment. This will be conducted using a power point presentation delivered by the investigator. This presentation includes an opportunity to practice tummy time together as a group (the investigator will have a doll to demonstrate tummy time positions). The intervention will commence the week following the third week of the usual care session (figure 2).

Primary outcome

The primary outcome will be the amount of infant tummy time assessed using the GENEActiv accelerometer. This method is feasible and has been validated for this participant population.[21] Both groups (intervention and control) will be asked to attach the GENEActiv accelerometer on their infant's right hip (secured with a strap) for three, 24-hour periods over 1 week. This measure will be taken in the week following the completion of the intervention. The device will be initialised at 30 Hz, with data collected in 1 s epochs and analysed as per the validation study.[21] Wear and non-wear time will be classified using temperature and z-axis cut points.[22] One of the research assistants (blinded to group) will have a face time call with the participant. During this call, they will demonstrate how to put the accelerometer on their baby (right hip, facing outwards). The accelerometer is used to measure the amount of tummy time the baby has participated in in the week post the intervention or, if in the control group, 4 weeks post the usual care sessions (so at the same time as the intervention mothers).

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
	Usual care online session (Recruitment)	Usual care walking group	Usual care walking group	Intervention online session	Intervention WhatsApp	Intervention WhatsApp	Intervention WhatsApp	Intervention WhatsApp	Follow-up assessments
Intervention group									
Control group									

Shaded area represents involvement

Figure 2 Schedule of enrolment, usual care, intervention and assessments.

At baseline and post intervention, all mothers will be asked to complete a questionnaire over the phone with a research assistant (online supplemental file 1). This will provide demographic and self-reported information regarding their infant's activities. Process measures such as the number of messages sent and received via WhatsApp and attendance to the online education session and usual care sessions will also be collected.

Sample size

Sample size calculations are based on detecting a difference in the amount of tummy time provided to an infant. From the pilot RCT,[18] the post mean (SD) objective measure for tummy time for the intervention group was 30.3 min (32.4) and 16.6 min (10.5) for the control group. Based on the calculation from https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html, using a significance of 0.05 and desired power of 0.80, the sample size required is approximately 56 mother/infant pairs in each of the intervention and control arms (N=112). It is estimated that 22 groups (6–8 babies per group) will be required to recruit to account for uptake of those interested in participating and dropout rate (10%).

Randomisation and blinding

Participants (mother/infant dyads) will be randomised to intervention or usual care (control) after baseline data collection. Randomisation to receive the intervention or usual care (control group) will be determined by a computer-generated random numbers programme, conducted by a researcher who is not part of the research team and will be blinded to group allocation and participant information. The information obtained from the questionnaire (phone interview) will be taken by a research assistant blinded to group allocation. To avoid observer effect (Hawthorne effect), mothers will not be told that the accelerometer is specifically for measuring the amount of tummy time. They will only be told the accelerometer is measuring the infant's physical activity.

Analyses

Linear mixed models will be used to determine differences between intervention and control groups in changes in the primary outcome between baseline and post intervention. Intention-to-treat principles will be followed, with all participants analysed in the group in which they are randomised. To calculate group mean estimates, the direct likelihood estimation method will be used to deal with any missing data (assuming that data are missing at random). Covariates will include sex, age, socioeconomic status and accelerometer wear time.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research other than the input from the participants and outcomes from the pilot RCT.[18]

DISCUSSION

This paper describes the rationale and protocol for an RCT that aims to evaluate the effectiveness of a multicomponent intervention delivered in postnatal mothers' groups on infant tummy time. It is based on current evidence supporting the importance of tummy time to improve motor development[2–8 23] and a successful pilot RCT targeting parents of infants. The pilot RCT included a group tummy time session, the use of WhatsApp social media and accelerometers (GENEActiv) to objectively measure the amount of tummy time the infant received.[18] The aim of this study is to expand the pilot to a full-scale RCT that is adequately powered to determine the effectiveness of the intervention in increasing infant adherence to the WHO Physical Activity Guidelines.

Strengths of this study are the use of a process (mothers' groups) already in place in existing health districts. As such, any positive findings can be more easily disseminated into clinical care. In addition, the use of the online delivery platform and mobile phone application enhances the potential for the scale up of the intervention to other areas. Limitations of this study are the unknown feasibility of the efficacy of the education component being delivered online and the accelerometer burden for mothers participating in this study. The possible implications of the limitations to the study could be the effectiveness of the intervention to produce behaviour change and needing to rely on subjective report of tummy time rather than the accelerometer respectively. To account for the possible limitations, the mothers will be provided with direct support from researchers (ie, facetime or phone call to answer any questions or to trouble shoot any difficulties) or additional time to use the accelerometer should it be required.

The findings of this study will be able to inform the development of practically based strategies to support clinicians, educators, parents and their infant reach optimum health outcomes. The study protocol, which follows the CONSORT guideline,[24] will enable the scientific assessment of the effectiveness of this intervention on the amount of tummy time an infant receives.

Ethics and dissemination

The University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee approved the study (2020/ETH02970). Dissemination plan is publication, staff training and conference presentations (written by the investigators of this study). Any modifications to the protocol, presence of adverse events etc will be submitted to the ethics committee for review and subsequently uploaded into the trial registry.

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Competing interests None declared.

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REFERENCES

1 World Health Organisation. Guidelines on physical activity sedentary behaviour and sleep for children under 5 years of age, 2019. Available: https://apps.who.int/iris/bitstream/handle/10665/311664/9789241550536-eng.pdf?sequence=1&isAllowed=y
2 Dudek-Shriber L, Zelazny S. The effects of prone positioning on the quality and acquisition of developmental milestones in four-month-old infants. *Pediatr Phys Ther* 2007;19:48–55.
3 Kuo Y-L, Liao H-F, Chen P-C, *et al*. The influence of wakeful prone positioning on motor development during the early life. *J Dev Behav Pediatr* 2008;29:367–76.
4 Majnemer A, Barr RG. Influence of supine sleep positioning on early motor milestone acquisition. *Dev Med Child Neurol* 2005;47:370–6.
5 Monson RM, Deitz J, Kartin D. The relationship between awake positioning and motor performance among infants who slept supine. *Pediatr Phys Ther* 2003;15:196–203.
6 Russell DC, Kriel H, Joubert G. Prone positioning and motor development in the first 6 weeks of life. *South African Journal of Occupational Therapy* 2009;39:11–14.
7 Salls JS, Silverman LN, Gatty CM. The relationship of infant sleep and play positioning to motor milestone achievement. *Am J Occup Ther* 2002;56:577–80.
8 Hewitt L, Kerr E, Stanley RM. Effects of tummy time and prone positioning ability on infant health outcomes: a systematic review. *Pediatrics* 2020;145:e20192168.
9 Hutchison BL, Thompson JMD, Mitchell EA. Determinants of nonsynostotic plagiocephaly: a case-control study. *Pediatrics* 2003;112:e316.
10 van Vlimmeren LA, van der Graaf Y, Boere-Boonekamp MM, *et al*. Effect of pediatric physical therapy on deformational plagiocephaly in children with positional preference: a randomized controlled trial. *Arch Pediatr Adolesc Med* 2008;162:712–8.
11 van Vlimmeren LA, van der Graaf Y, Boere-Boonekamp MM, *et al*. Risk factors for deformational plagiocephaly at birth and at 7 weeks of age: a prospective cohort study. *Pediatrics* 2007;119:e408–18.
12 Zachry AH, Nolan VG, Hand SB, *et al*. Infant positioning, baby gear use, and cranial asymmetry. *Matern Child Health J* 2017;21:2229–36.
13 Gross RS, Mendelsohn AL, Yin HS, *et al*. Randomized controlled trial of an early child obesity prevention intervention: impacts on infant tummy time. *Obesity* 2017;25:920–7.
14 Hesketh KD, Downing KL, Campbell K, *et al*. Proportion of infants meeting the Australian 24-hour movement guidelines for the early years: data from the Melbourne infant program. *BMC Public Health* 2017;17:856.
15 Palmer CF, Rindler D, Leverone B. Moving into tummy time, together: touch and transitions aid parent confidence and infant development. *Infant Ment Health J* 2019;40:277–88.
16 Wen LM, Baur LA, Simpson JM, *et al*. Effectiveness of an early intervention on infant feeding practices and "tummy time": a randomized controlled trial. *Arch Pediatr Adolesc Med* 2011;165:701–7.
17 Bandura A. Health promotion by social cognitive means. *Health Educ Behav* 2004;31:143–64.
18 Hewitt L, Stephens S, Spencer A, *et al*. Weekly group tummy time classes are feasible and acceptable to mothers with infants: a pilot cluster randomized controlled trial. *Pilot Feasibility Stud* 2020;6:155.
19 Downing KL, Salmon J, Hinkley T, *et al*. Feasibility and efficacy of a parent-focused, text message-delivered intervention to reduce sedentary behavior in 2- to 4-year-old children (mini movers): pilot randomised controlled trial. *JMIR Mhealth Uhealth* 2018;6:e39.
20 Huang C, Wang Y, Li X, *et al*. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *The Lancet* 2020;395:497–506 https://doi.org.acs.hcn.com.au/
21 Hewitt L, Stanley RM, Cliff D, *et al*. Objective measurement of tummy time in infants (0-6 months): a validation study. *PLoS One* 2019;14:e0210977.
22 Hewitt L, Okely AD, Stanley RM, *et al*. Validity of GENEActiv accelerometer wear and nonwear time for use in infants. *J Phys Act Health* 2021;18:488–94.
23 Uzark K, Smith C, Yu S, *et al*. Evaluation of a "tummy time" intervention to improve motor skills in infants after cardiac surgery. *Cardiol Young* 2021:1–6.
24 Eysenbach G. CONSORT-EHEALTH: implementation of a checklist for authors and editors to improve reporting of web-based and mobile randomized controlled trials. *Stud Health Technol Inform* 2013;192:657–61.