

Goal feedback from whom? A physical activity intervention using an N-of-1 RCT

Erin E. Brannon^a, Christopher C. Cushing^b*, Ryan W. Walters^c, Christopher Crick^d, Amy E. Noser^e and Larry L. Mullins^f

^aPediatric Pain Rehabilitation Program, Cleveland Clinic Children's Hospital, Cleveland, OH, USA; ^bClinical Child Psychology Program, University of Kansas, 2011 Dole Human

Development Center, Lawrence, KS, USA; ^cDepartment of Medicine, Creighton University,

Omaha, NE, USA; ^dComputer Science Department, Oklahoma State University, Stillwater, OK.

USA; ^eClinical Child Psychology Program, University of Kansas, 2020 Dole Center, Lawrence,

KS, USA; ^fDepartment of Psychology, Oklahoma State University, Stillwater, OK, USA

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Objective: Adolescents are not meeting the recommended guidelines for physical activity. Social support and self-regulatory skills are two factors known to impact physical activity and sedentary behaviour. The study sought to examine how targeting feedback as part of a self-regulatory process could increase physical activity, and the individual who should be providing the feedback.

Design: The study utilised an aggregated N-of-1 RCT which allows for an iterative process of intervention development, and examines variability within participants to answer the question *for whom did the intervention work*. Ten adolescents (ages 13–18) set a daily physical activity goal. Adolescents received a SMS text message providing feedback on goal attainment daily from a parent, peer, behavioural health specialist; or no text message (control).

Main Outcome Measures: A bioharness heart rate monitor assessed heart rate as proxy for goal attainment. Adolescents also self-monitored their physical activity in the Calorie Counter and Diet Tracker by MyFitnessPalTM app (commercially available).

Results: Intervention demonstrated a significant effect for 30% of the sample in increasing MVPA ($M_{increase} = 52 \text{ min}$), with no significant effect on sedentary behaviour.

Conclusion: A single occasion of text messaging from the right person can produce changes, however, careful consideration should be given to who provides the feedback.

Keywords: physical activity; adolescent; mhealth; RCT

Engagement in regular physical activity is associated with desirable health outcomes such as aerobic fitness, healthy blood pressure, decreased prevalence of obesity, overall better psychological health (Janssen & LeBlanc, 2010; Sallis & Patrick, 1994). Given the benefits of regular physical activity, it is recommended that children between the ages of 6 and 17 years participate in at least 60 min of moderate-to-vigorous physical activity

^{*}Corresponding author. Email: christopher.cushing@ku.edu

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(MVPA) daily (Department of Health & Human Services, 2008; UK Department of Health, 2011; World Health Organization, 2010). However, research on physical activity patterns indicate that MVPA significantly declines between the ages of 9 and 15 years (Nader, Bradley, Houts, McRitchie, & O'Brien, 2008). In fact, adolescents spend a large amount of their time in sedentary activity with average values of nine hours per day for total sedentary time (Cliff et al., 2016; Matthews et al., 2008). Thus, increasing adoption of health promoting behaviours and decreasing sedentary activity, is a significant public health concern (Schwarzer, 2008).

Two factors that are known to modify health behaviours are the use of self-regulatory skills and social support (Patrick et al., 2001; Van der Horst, Paw, Twisk, & Van Mechelen, 2007). Self-regulatory skills from cybernetic control theory (Carver & Scheier, 1982) such as goal-setting, self-monitoring, goal review have demonstrated efficacy in changing physical activity levels in adults (Michie, Abraham, Whittington, McAteer, & Gupta, 2009; Sniehotta, Presseau, Hobbs, & Araujo-Soares, 2012) and adolescents (Aittasalo, Miilunpalo, Kukkonen-Harjula, & Pasanen, 2006; Cushing & Steele, 2010). Social support is a modifiable correlate of physical activity that can be targeted directly by interventions. Social support for physical activity refers to individuals who facilitate engagement in physical activity, and has been shown to impact physical activity and sedentary behaviour in children and adolescents (Biddle, Petrolini, & Pearson, 2014; Taylor, Baranowski, & Sallis, 1994). There are a number of meaningful individuals in an adolescent's life that could potentially provide this social support (Cushing, Brannon, Suorsa, & Wilson, 2014). For example, parental support, including verbal encouragement and instrumental support (e.g. transportation), shows a strong positive correlation with children and adolescents' level of physical activity (Gustafson & Rhodes, 2006; Van der Horst et al., 2007). Parents can also provide social support for reducing sedentary activity by setting goals, creating a plan for turning off screens and encouraging active behaviours (Biddle et al., 2014).

Although parents are important agents for encouraging youth physical activity at younger ages, adolescents spend more time with peers who then exert more influence on health behaviours (Voorhees et al., 2005). Thus, peers can have a significant effect on physical activity in adolescence in the context of mentorship (Black et al., 2010; Smith, 2011), through the use of peer support (Beets, Vogel, Forlaw, Pitetti, & Cardinal, 2006), encouragement (Duncan, Duncan, & Strycker, 2005) and within common motivations of peer acceptance and increased friendship quality (Fitzgerald, Fitzgerald, & Aherne, 2012). Receiving targeted feedback on health behaviours by a healthcare professional has also demonstrated significant changes in improving adolescent health behaviours (Patrick et al., 2001, 2006).

Although research to date has examined parent, peer and healthcare provider interventions at the group level, static interventions do not account for or adapt to the within-person variability that exists in lifestyle behaviours; nor does the research examine feedback singularly as a form of intervention. This inflexibility likely limits the knowledge that can be derived from any given intervention trial or the active ingredients of intervention trials (Adams et al., 2013). Calls in the literature underscore identification of the active ingredients and their exerting effects on behaviour change (Craig et al., 2008). To date, questions regarding the theoretical underpinnings of individual behaviour change, and the specific components of interventions for increasing physical activity in adults has been well-studied (Hobbs, Dixon, Johnston, & Howie, 2013; Sniehotta et al., 2012). There is developing research on the clinical utility of N-of-1 RCT as a novel methodology to answer these important questions at an idiographic level (e.g. Nyman, Goodwin, Kwasnicka, & Callaway, 2016). The applicability of this type of methodology or examination of feedback providers on physical activity has yet to be examined in a child or adolescent population.

Examining the effectiveness of an intervention at the level of the individual is vital for articulating profiles of which individuals will respond to which treatment condition. Parsing out the active ingredients in intervention packages, such as those based on Carver and Scheier's control theory, is in line with the Medical Research Council's recommendations for the evaluation of complex interventions (UK Medical Research Council, 2008; Carver & Scheier, 1982). Therefore, the next step for developing tailored interventions is to examine whether feedback from varying sources of social support impacts the effectiveness of interventions. Armed with this information, behavioural scientists can then use the dosage or type of feedback to create decision rules linking characteristics of the individuals with specific levels and types of programme components. Thus, the aims of the current study are to examine: (1) for whom the feedback on goal attainment works and (2) which of several variants of the feedback provider increases physical activity participation and decreases time spent in sedentary behaviour.

Methods

Participants

Thirteen adolescents were recruited for the current study (15 approached) via convenience sampling through the use of flyers. Flyers were placed in public places (e.g. coffee shops, recreational facilities), as well as throughout the university of the first author, and an email was sent to university faculty. However, three participants withdrew prior to beginning any study procedures. The inclusion criteria required that an adolescent between 13 and 18 years of age, and report less than 60 min of physical activity per day. In the final sample, participants included three boys and seven girls identified using community-based recruitment. Nine participants self-identified as Caucasian with one self-identifying as Hispanic, and participants had a mean age of 16.7 years (SD = .95). Regarding socio-economic status, eight had a family income greater than \$60,000, one between \$50,000 and \$60,000 and one between \$40,000 and \$50,000. Participants were compensated up to \$40 for their participation in the study based on their compliance to the protocol (e.g. \$1 each day for wearing equipment and \$15 for completing at least 75% of study surveys). At the initial visit, participants were equipped with a Zephyr Bioharness 3.0 heart rate monitor to be worn 12 h each day and an Actigraph accelerometer (Actigraph wActi Sleep-BT) to be worn on their non-dominant hand 24 h per day.

Measures

Moderate to vigorous physical activity and sedentary behaviour

Total movement was measured using the Actigraph wActi Sleep-BT accelerometer (Actigraph LLC, Pensacola, FL) and was the primary outcome variable. Actigraph is a validated wireless activity monitor that provides an objective measure of physical activity, sedentary activity and sleep/wake measurements. Actigraph assessments have been shown to be highly correlated with direct observation assessment in children (McClain, Abraham, Brusseau, & Tudor-Locke, 2008). The device was worn on the non-dominant hand of each adolescent for 24-h a day and is in accordance with the current National Health and Nutrition Examination Survey (NHANES) protocol (Troiano et al., 2008). Data were filtered such that a valid day was defined as having 10 or more hours of wear time while awake, which is consistent with large epidemiological studies (Troiano et al., 2008). Cut points were derived from a recent article providing MVPA for wrist-placement accelerometry in children ages 8–12 (Chandler, Brazendale, Beets, & Mealing, 2015).

Real-time physical activity assessment

The Zephyr BioHarness 3.0 (Zephyr Technology, Auckland, New Zealand) is a wireless physiological monitoring device. The Bioharness was worn around the chest directly across the rib cage just below the sternum. The device stores and transmits vital sign data including heart rate, respiration rate, body orientation and activity.

The Bioharness physiological monitoring device was utilised for real-time physical activity data capture to inform the type of feedback participants received. The Bioharness was synced to the ZephyrLife mobile application via Bluetooth that allowed participants to view their heart rate and breathing rate in real time. Participant data were also transmitted to a web portal that graphically displayed physiological data for each participant allowing study staff to assess the participant's goal attainment daily. Goal attainment was derived from the physiological heart rate data, to determine if participants were in the Max heart rate or aerobic heart rate (i.e. (220 - age) * .60) for the specified goal each day. In circumstances where heart rate data could not be transmitted to the web portal due to limited connectivity ($\approx 62\%$ of all observations), goal attainment was determined from the participant's self-reported physical activity, as described below. Poor connectivity was related to difficulty of data transmission via wifi, such that, when the bioharness did not have ready access to wifi the connection was poor. The data from the bioharness was used solely to provide information that informed feedback and did not affect outcome data.

Self-reported physical activity

Participants provided self-reported physical activity using the Calorie Counter and Diet Tracker within the MyFitnessPalTM mobile application, which has been shown to incorporate several evidence-based strategies for health behaviour change including goal setting, self-monitoring, goal review and social support (Brannon & Cushing, 2015). Participants were instructed to record their daily physical activity after which it was visible to the study staff.

Procedure

Consistent with cybernetic control theory (Carver & Scheier, 1982), the intervention included self-regulation strategies defined by goal-setting, self-monitoring, goal review and feedback. To standardise the goal-setting process, participants were provided

instruction on the Centre for Disease Control recommendations for adolescents between the ages of 13 and 18 that recommend 60 min of moderate-to-vigorous physical activity (MVPA) daily (Centres for Disease Control and Prevention, 2015). Adolescents then set a personal goal for minutes of daily physical activity. Participants were instructed to perform any activity of choice as long as it met the definition of MVPA (e.g. requires a moderate amount of effort that increases heart rate and makes it difficult to carry a conversation).

Self-monitoring occurred at the end of each day using the Calorie Counter and Diet Tracker within the MyFitnessPalTM mobile application (https://www.myfitnesspal.com), in which participants selected their physical activity from an auto-populated list of common activities (e.g. jogging, swimming) and recorded the total minutes a given activity was performed. There was no standardisation process for goal-review as this aspect of self-regulation was completed by the study staff, such that, the staff would review real-time heart rate data via the Zephyr portal or the self-reported physical activity within the MyFitnessPalTM app. In circumstances where heart rate data could not be transmitted to the web portal due to limited connectivity ($\approx 62\%$ of all observations), goal attainment was determined from the participant's self-reported physical activity, as described below.

Participants were provided daily feedback using four randomly-assigned conditions. On intervention days, each participant received feedback via one standardised text message from either a behavioural health specialist (study staff), a parent (family), or a peer. On control days, no feedback text message was received, but the participant retained access to the MyFitnessPalTM mobile application (i.e. active control). Randomisation of conditions occurred across study days within each participant receiving a Latin square design to diminish order effects (Brooks, 2012). The number of intervention days was held constant across participants to ensure an equal 'dose' of each level of the intervention (6 days of each intervention level). The power analysis (G^* power programme) indicated that four groups with six observations each would result in a significant finding 91% of the time if a small effect (i.e. f = .25) was present in the population. Therefore, adolescents participated in the study for a total of 24 days. The standardised text message was delivered to the participant based on their goal attainment for that day. Each night between 7 and 8 pm, the feedback message was sent by study staff to the designated feedback provider for that day. Specifically, if the participant met their physical activity goal for the day, the feedback provider was instructed to send the following message: 'Hey [Insert name]. Great job meeting your physical activity goal for the day. Keep up the great work.' However, if the participant did not meet their physical activity goal, the feedback provider was instructed to send: 'It looks like you didn't meet your goal for the day. Try going for a short walk to get that heart rate up.' It was expected that the feedback provided would modify physical activity on the following day. On average, participants met their physical activity goal 25% of the time.

Statistical analysis

Treatment days were lagged by one day to account for expected carryover effects. To determine for whom the feedback conditions worked, one-day lagged mean MVPA and minutes engaged in sedentary activity were compared between the no-feedback control

condition and each feedback condition. This allowed for understanding of whether feedback from any one individual was greater than not receiving feedback on goal attainment. The multi-level structure of the data resulting from the nesting of repeated occasions within participants was collapsed using fixed effects to account for all individual differences in the average amount of MVPA and sedentary time, as well as individual differences in average MVPA and sedentary time between each treatment condition and control condition (Hoffman, 2015). That is, we estimated an individual fixed effect for each participant via indicator coding (aka, dummy coding) as well as a treatment-by-participant fixed interaction effect. All models were estimated using SAS v. 9.4 (SAS, Inc., Cary, NC) using restricted maximum likelihood (REML) estimation; denominator degrees of freedom were estimated using the Satterthwaite method. The significance of additional variance components were evaluated using likelihood ratio tests (i.e. $-2\Delta LL$), with degrees of freedom equal to the number of new variance components, whereas the significance of fixed effects were evaluated with individual Wald tests (i.e. estimate/SE). Given the novelty of these feedback conditions, no adjustment was employed for multiple comparisons; therefore, p < .05 indicated statistical significance.

Results

For both MVPA and sedentary behaviour, estimating heterogeneous residual variances, significantly improved model fit, $-2\Delta LL(9) = 20.93$, p = .013 and $-2\Delta LL(9) = 22.85$, p = .007, respectively. As such, for both outcomes, each participant was allowed to have his or her own residual error variance estimate. The final models for MVPA and sedentary behaviour were based on 157 and 158 observations, respectively.

Idiographic findings: MVPA

A statistically significant participant-by-feedback condition interaction effect was observed for MVPA, F(27,5.17) = 18.07, p = .002, indicating the effect of a given feedback condition on MVPA varied between participants. Model estimated means and standard errors for MVPA for each participant by feedback condition are presented in Table 1.

Three participants demonstrated significant increases in MVPA when receiving feedback compared to not receiving feedback on goal attainment. Specifically, participant 1 increased their MVPA relative to the control condition following feedback from the behavioural health specialist by an average of 26.0 min (95% CI = 7.7 to 44.3). Participant 5 increased their MVPA relative to the control condition following feedback from a parent and behavioural health specialist, by an average of 83.5 min (95% CI = 70.1 to 96.9) and 73.5 min (95% CI = 60.1 to 86.9), respectively. Lastly, relative to the control condition, participant 8 averaged a 52.5 min increase in MVPA following parental feedback (95% CI = 18.5 to 86.5) and a 42.0 min increase following peer feedback (95% CI = .3 to 83.7). The results suggest that some adolescents respond to feedback on goal attainment to increase physical activity, however, a single intervention approach is not likely to be effectively for helping adolescents increase physical activity.

Participant	Control	Parent	Peer	Behavioural health	Missing data (%)
1	5.8 (6.0)	11.5 (5.9)	13.5 (5.6)	31.8* (5.6)	4
2	27.5 (9.3)	7.3 (11.3)	8.6 (10.1)	9.3 (9.3)	12.5
3	29.8 (6.8)	39.6 (7.5)	42.3 (6.8)	43.0 (6.8)	0
4	20.5 (10.4)	28.0 (7.3)	11.0 (8.5)	33.0 (7.3)	41.7
5	2.5 (1.8)	86.0* (2.6)	.5 (1.8)	76.0* (2.5)	72
6	13.2 (5.2)	27.7 (5.2)	11.7 (5.2)	22.5 (5.2)	0
7	24.7 (8.1)	16.8 (8.1)	23.3 (8.1)	28.0 (8.1)	0
8	21.0 (7.6)	73.5* (7.6)	63.0* (10.7)	36.5 (7.6)	70.8
9	16.0 (15.5)	9.0 (11.0)	27.0 (15.5)	41.5 (11.0)	70.8
10	43.0 (11.0)	55.3 (12.3)	51.85 (12.3)	62.0 (12.3)	20.8
Overall	22.4 (2.8)	30.0 (2.9)	24.5 (2.9)	34.1 (2.7)	32

Table 1. Estimated mean MVPA (SE) in minutes for each feedback condition between and within participants.

Notes: Participants 2, 3, 4 did not complete the study. Missing data refers to days the participant did not wear the accelerometer for a total of 10 h during the daytime hours. *p < .05.

Idiographic findings: minutes engaged in sedentary behaviour

For sedentary behaviour, the participant-by-treatment condition interaction was not statistically significant, F(27, 10.8) = 2.05, p = .107, indicating that the feedback conditions had a similar effect across participants. After removing this non-significant twoway interaction effect, the main effect of feedback condition was not statistically significant, F(3, 74.7) = 1.28, p = .288, indicating that no feedback condition significantly decreased sedentary time relative to the control condition. The average minutes engaged in sedentary behaviour across the conditions was 609.4 (17.8), 646.4 (18.3) and 651.0 (17.6) for the parent, peer and behavioural health conditions, respectively. Similarly, participants engaged in 642.2 (18.2) minutes of sedentary time during the control conditions. Relative to control, the parental feedback condition was associated with approximately 32.8 fewer minutes of sedentary behaviour (95% CI = -80.9-15.4), whereas the peer and behavioural health specialist feedback conditions averaged slight increases in sedentary time by 4.3 min (95% CI = -44.9-53.4) and 8.8 min (95% CI = -39.1-56.7), respectively. Overall, receiving feedback on goal attainment does not appear to significantly decrease engagement in sedentary behaviour.

Discussion

The purpose of the study was to test the importance of tailored feedback on physical activity goal attainment from three varying sources. Secondly, this was a preliminary study to demonstrate the potential utility and value of N-of-1 RCT designs to identify active ingredients in intervention packages. Three participants in the study demonstrated an increase in physical activity when receiving feedback on goal attainment. Of note, each participant also responded differently to the feedback providers, with one participant responding favourably to only one feedback provider (i.e. behavioural health specialist) and two participants responding to multiple feedback providers (i.e. parent, behavioural health specialist, peer). Given the within-person variability that exist in life-style behaviours, there is no surprise that the variant of feedback would differ across

participants. As the literature highlights, feedback from all three providers has been effective in modifying health behaviours (e.g. Fitzgerald et al., 2012; Patrick et al., 2006; Van der Horst et al., 2007). The idiographic findings across participants highlights the differences in relationships with each feedback provider, in that, some participants may have responded to the authority of an unknown behavioural health specialist, while other participants may have operated on more social desirability to impress a peer. At the same time, parents spend a great deal of time with their children and may have provided more prompting or encouragement to complete their physical activity within the context of the home. Unfortunately, there was no individual treatment effect on decreasing engagement in sedentary behaviour across participants.

As the field of health psychology moves towards more adaptive interventions, waste can be reduced by tailoring the intervention to the needs of the individual to optimise the treatment effect. In fact, behavioural scientists are often challenged with the task to answer important questions that often have insufficient empirical evidence to guide the intervention. Our study answers a call in the literature to identify treatment variables that may impact intervention effectiveness such as who should be providing feedback, and could act as a tailoring variable to indicate how to further individualise treatment. The field is only beginning to capitalise on the use of N-of-1 studies to elucidate the within person variability that affects intervention effectiveness, but also informs the intensity, modality and method of interventions for personalisation treatment (Hobbs et al., 2013; Nyman et al., 2016; Sniehotta et al., 2012). The focus on empirically testing individual treatment components may produce more uniform treatment. Therefore, patients' response to treatment from feedback provider at the initial stage could be used to assist in randomisation of patients at the second stage of an adaptive intervention. Feedback on goal attainment from a parent, peer or healthcare provider could be considered as a tailoring variable as is demonstrated in the current study. Findings from this study mirror that of the adult literature in identifying the effectiveness of self-regulation components in changing physical activity behaviour (Nyman et al., 2016). Our findings are also consistent with literature highlighting the improvements in physical activity when tailored feedback is provided (Bauer, de Niet, Timman, & Kordy, 2010; Fjeldsoe, Marshall, & Miller, 2009; Suggs, 2006). Unfortunately there is a paucity of research utilising N-of-1 designs in child and adolescent samples, which could strengthen the effectiveness of interventions.

Future studies should involve larger samples, which would provide statistical power to allow examination of the question of *why the intervention works for some participants and not others* (Cushing, Walters, & Hoffman, 2014), and by incorporating additional moderators or mediators of intervention effectiveness. Further examination of psychological and cognitive constructs such as self-efficacy, readiness and motivation for physical activity, in addition to perception of social support is warranted (Brown, Hume, Pearson, & Salmon, 2013). Understanding those factors that influence intervention effectiveness and elucidate what makes intervention components favourable to each individual is vital in understanding tailoring variables that can be incorporated into adaptive interventions. Future iterations should also examine the benefit of an automated text message system designed to provide appropriate goal-setting and feedback on goal attainment, or a text message intervention that incorporates social support from family and peers.

The findings should be interpreted in light of several limitations. Due to the nature of N-of-1 RCTs and dependence on participant engagement, there was a large amount

of missing data for some participants. Despite the missing data, the results of this preliminary study are suggestive of an effect for tailored feedback on goal attainment and warrant replication. A manipulation check was put in place to assess whether the participants were receiving the text messages from parents and peers as indicated in the protocol. Due to the logistics of data collection, the manipulation check was completed prior to the participant receiving the feedback. Future studies should incorporate a manipulation check that not only assesses whether text messages were sent, but also whether the content of the message was standardised. The socio-economic status of the families was primarily middle class which may decrease the generalisability to lower socio-economic status families.

While every effort was made to hold extraneous variables constant, we do not have knowledge about changes that may have occurred as a result of participating in the study. For example, it may be that participants had a global shift in their social ecological ecosystem in that individuals (e.g. parents, peers) provided general social support for physical activity even when they were not instructed to do so. Or, it may be that the app, which was designed to be an attention control, may have created a change due to the inclusion of evidence-based strategies. Comparing the data from the current study with a control group receiving no intervention could provide additional clarity on these questions. Mobile health technologies that incorporate the use of text messages stand to be a viable option for health promotion interventions (Fjeldsoe et al., 2009), specifically physical activity interventions (Bauer et al., 2010; Stephens & Allen, 2013).

The strengths of this study are two-fold: utilising a novel research methodology to capitalise on individual variability, and the reliance on an evidence-based behaviour change model (Carver & Scheier, 1982) that lends itself to mobile application. Additionally, this study highlights the need to take individual preference into account when designing interventions and demonstrates the heterogeneity that exist in patient preference and subsequent impact on intervention effectiveness. Finally, the study addresses calls in the literature to examine individual and temporal factors, tested separately from a complex intervention, to identify the features that lead to long-term success of behaviour change (McDonald, Araújo-Soares, & Sniehotta, 2016).

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