Research Proposal

04/08/2021

Study Title: SCI Step Together: Improving Physical Activity Participation Among Individuals With SCI Who Ambulate

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Study Sites: 1. University of British Columbia, Kelowna, BC, Canada

Sponsors: Social Sciences and Humanities Research Council
WorkSafe BC Research Training Award
CDPP Funding

SUMMARY

Purpose: To assess the feasibility and acceptability of a mobile health application (mHealth app) to increase quantity and quality of physical activity experiences among ambulators living with spinal cord injury.

Justification: Individuals living with spinal cord injury (SCI) who walk participate in less physical activity than individuals with SCI who use wheelchairs. Lower levels of physical activity may be due to barriers such as increased pain and fatigue, lack of time, and lack of knowledge. Additionally, in the second study of my dissertation, we identified that action and coping planning, goal conflict, and skills are associated with increased physical activity levels. Quality of physical activity experiences also play an important role in participation. Recently, elements of positive and negative physical activity experiences, in addition to factors that influence quality, were classified among individuals with SCI who ambulate in the third study of my dissertation. These elements mapped onto the Quality Participation Framework (i.e., autonomy, belongingness, challenge, engagement, meaning, mastery) and the conditions aligned with the Quality Parasport Participation Framework (intrapersonal, social, program, and physical). Despite the recent focus on understanding factors that enhance both quantity and quality of physical activity participation, there are no physical activity interventions available targeted specifically for individuals with SCI who walk. Therefore, this study will develop and assess the acceptability and feasibility of a mHealth app to increase the quantity and quality of physical activity among ambulators with SCI according to evidence from the previous two studies.

Objectives: The main objectives are to: (a) collaboratively develop and implement the 8-week program delivered through a mHealth app, (b) qualitatively evaluate the subjective experiences of the mHealth program (i.e., engagement, acceptability, and feasibility) and (c) quantitatively evaluate the engagement, acceptability, and feasibility, in addition to behaviour change factors, leisure-time physical activity levels, quality of physical activity participation, and employment.

Study Design/Methods: This randomized controlled trial (RCT) will recruit a total of 20 ambulators with SCI across Canada and the United States. Consenting participants will be randomized into either the wait-list control or intervention group. The wait-list control group will be asked to continue their everyday routine and not engage in any new physical activity or health program. The intervention group will participate in an 8-week program (also termed intervention) delivered through a mHealth app, consisting of education modules, worksheets, peer support and behavioural support. The intervention will aim to increase physical activity quantity and quality. Assessments will take place at baseline, 4-weeks, and 8-weeks for both the control and intervention groups. These assessments include social support, action control, basic psychological needs, autonomous motivation, behaviour change domains, leisure-time physical activity, quality of exercise and sport experiences, and employment hours and financial resources. After completing the final assessments at 8-weeks, participants in the intervention group will be invited to participate in an interview to get a better understanding of their satisfaction with the program. Only investigators on the study will have access to the de-identified data, which will be stored on a password-protected folder in UBC's One Drive.

Analyses: Demographic information will be used to describe the sample. Descriptive statistics will be used to characterize the sample using means and standard deviations for continuous variables and proportions and frequencies for categorical variables. Mixed effect models will be used to test for statistically significant different ($p<0.05$) in quantitative outcomes. Qualitative interviews will be transcribed, and a content analysis of the interview transcripts will be guided by an inductive approach.

Table of Contents

1. BACKGROUND AND PROGRAM RATIONALE

1.1 Physical activity among individuals with SCI who ambulate

Individuals living with SCI who ambulate participate in significantly less leisure-time physical activity (LTPA) than individuals with SCI who use a wheelchair (Martin Ginis et al., 2010). Participation in low levels of LTPA may mean that ambulators with SCI are not obtaining the associated health benefits, such as increased cardiovascular fitness, or reduced pain and fatigue (DiPiro et al., 2016). This group may not be participating in LTPA due to unique barriers such as pain (Roberton et al., 2011), lack of group identity (Martin Ginis, Papathomas, et al., 2017), lack of interest (Scelza et al., 2005), and lack of evidence-informed interventions to increase the quantity of LTPA participation. Recently, a cross-sectional study found that action and coping planning, goal conflict, and skills predict LTPA behaviour among ambulators with SCI (Lawrason & Martin Ginis, In press). Interventions informed by behaviour change theory that use strategies to target these behaviour change constructs could be valuable when aiming to increase the quantity of LTPA among ambulators with SCI.

1.2 Quality participation in physical activity

There is also a need to understand how to improve the quality of LTPA participation (i.e., subjective perceptions and experiences; Hammel et al., 2008) among ambulators with SCI. The quality of LTPA experiences may be important for improving well-being, health (Labbé et al., 2019; McLean et al., 2014) and maintaining LTPA participation (Fong et al., 2020). A qualitative study using a pragmatic approach recently examined subjective experiences in LTPA among this population, informed by the Quality Participation Framework (Martin Ginis, Evans, et al., 2017) and the Quality Parasport Participation Framework (Evans et al., 2018) (Lawrason et al., In preparation). The study identified intrapersonal, social, program, and physical conditions that influence quality elements in LTPA (i.e., belongingness, meaning, mastery, engagement, challenge, and autonomy) (Lawrason et al., In preparation). These conditions may be targeted in an intervention to increase the quality of LTPA through behaviour change techniques such as goal setting (Michie et al., 2011). Behavioural support can increase quality through understanding the context of physical activity participation for ambulators with SCI, including experiences of ableism, feeling sidelined, and invisibility (Lawrason et al., In preparation).

1.3 Physical activity intervention design and implementation

Developing and implementing effective physical activity interventions requires a multifaceted approach. Using the person-based approach (Yardley, Ainsworth et al,. 2015) in combination with evidence, theory, and integrated knowledge translation (IKT, i.e., involving end-users throughout the research process; Graham et al., 2006) offers a unique and potentially impactful method for physical activity intervention development. To begin, the person-based approach aims to offer the groundwork for developing interventions which account for the context, perspectives, and lives of individuals who use them through mixed methods research (Yardley, Ainsworth, et al., 2015). As such, the person-based approach aligns well with IKT with the goal of involving end-users, and also with the concurrent use of theory and evidence (Yardley, Ainsworth et al., 2015). The person-based approach identifies strategies for

intervention planning, design, and development to ensure acceptability and feasibility for end-users throughout and is thus ideal for digital health interventions (Yardley, Ainsworth, et al., 2015; Yardley, Morrison et al., 2015).

Interventions that are evidence- and theory-based and use IKT can improve physical activity outcomes among individuals with SCI (e.g., Ma et al., 2020). One such theory is self-determination theory (SDT), which suggests that three basic needs are required for motivation and well-being: autonomy, competence, and relatedness (Ryan & Deci, 2000). SDT also posits that self-determined motivation lies on a spectrum from extrinsic (controlled) to intrinsic (autonomous) (Ryan & Deci, 2000). SDT aligns well with evidence from the study by Lawrason and Martin Ginis (In press) as planning can increase autonomous motivation (Sweet et al., 2017) and increasing competence through self-efficacy is a main goal (Ryan & Deci, 2000). Indeed, interventions can use behaviour change techniques that target SDT constructs (Sweet et al., 2017). Furthermore, SDT is inherently aligned with the Quality Participation Framework (Martin Ginis, Evans, et al., 2017), as more intrinsically motivating (or self-determined) physical activities are likely to be higher quality. Finally, recent evidence suggests that an 8-week SDT-informed telerehabilitation intervention can increase motivation and physical activity levels among individuals with SCI (Chemtob et al., 2019). Accordingly, using SDT may be a useful theory for informing a physical activity intervention that aims to increase quantity and quality of LTPA participation. Thus, we will use SDT as the framework to guide this intervention. Specifically, intervention components will target the three basic psychological needs in an effort to increase autonomous motivation to participate in LTPA (Ryan & Deci, 2000).

PURPOSE & HYPOTHESIS

Primary objective: The purpose of this project is to: (a) collaboratively develop and implement an intervention delivered through a mHealth app for persons with SCI who walk to increase the quantity and quality of physical activity, (b) evaluate the engagement, acceptability, and feasibility of the aforementioned intervention, and (c) assess primary outcomes of basic psychological needs, autonomous motivation, leisure-time physical activity levels, quality of physical activity participation, and employment.

Hypotheses: The primary hypothesis is that the program will be deemed an acceptable and feasible method of improving physical activity participation among individuals with SCI who ambulate. A secondary hypothesis is that the program will improve basic psychological needs and autonomous motivation to participate in LTPA. A tertiary hypothesis is that the program will increase leisure-time physical activity levels, quality of physical activity participation, and employment.

2. MEASURES (Appendix A)

The following section on Feasibility and Engagement will not require any additional effort or information from participants, but rather assesses the study progression to understand whether the intervention is feasible for future implementation.

Feasibility and Engagement

Feasibility will be assessed according to **process, resource, management**, and **scientific** indicators (Adamson et al., 2016; Learmonth & Motl, 2018).

Process feasibility assesses participant recruitment. A recruitment rate (dividing the total number of participants enrolled by the number of participants contacted) and eligibility rate (number of potential participants excluded from the total number of interested participants) will be calculated. We will aim to have a recruitment rate of 60% and eligibility rate of 55% as reported by Jeske and colleagues (2020) in a physical activity intervention for individuals living with SCI.

Resource feasibility assesses participation and monetary requirements of the study. Participation will be examined through retention rate (number of participants who completed at least some part of the intervention from those who were randomized) and adherence rate (number of participants who completed testing and follow-up measures). We will aim to have a retention rate of 90% (physical activity intervention for individuals with SCI; Jeske et al., 2020) to 100% (used at least one part of mobile health application; Smith et al., 2017) as reported by similar interventions. We will aim to have to have an adherence rate of 81-90% (Allin et al., 2020). We will assess the costs of the study as calculated by the total cost for producing the software and app, participant remuneration, and potential cost of the health behaviour coach.

Management feasibility assesses data management and safety reporting during the study. We will record the IRB approval time according to the total number of days from submission to approval notification including any amendment details as necessary. Next, we will report staff preparation and reporting time calculated as the time to: recruit partners, conduct partner interviews, analyze recommendations, recruit participants, liaise with participants (e.g., group allocation, answering questions), and enter and check all participant data (i.e., total minutes). Missing data items (i.e., questions not answered for testing) will be monitored for baseline and follow-up assessments.

Scientific feasibility assesses the safety, burden, and treatment effect of the study. Safety will be recorded as the number of health problems experienced by the participants over the course of the intervention. Demographic information will be established via a self-report questionnaire. We will describe measures for assessing participant satisfaction and burden below in the qualitative measures section. Compliance with the intervention will be calculated according to the number of participants who complete each weekly module. Although participant compliance is high for traditional physical activity interventions for people with SCI (88% to 91.7%; Brawley et al., 2013; Jeske et al., 2020), we expect much lower compliance for an app-based intervention. Notably, one intervention states that compliance ranges from 16% to 100% depending on the module. As such, we expect to see different compliance rates throughout the course of the intervention. Finally, treatment effects will be assessed according to the quantitative measures listed below.

Engagement with the app will be measured in different ways. First, we will measure compliance as stated above. Next, we will assess the number of times logged into the app over the course of 8-weeks. Finally, we will look at how long each participant spends logged into the app during each module. Previous research suggests that web users spend significantly longer on

interventions compared to app users, but app users log into interventions significantly more times than web users (Morrison et al., 2018).

Outcome Measures

The Psychological Need Satisfaction in Exercise Scale: This 18-item scale assesses the satisfaction of the psychological needs for exercise using a 6-point Likert scale ranging from 1 (false) to 6 (true) (Wilson et al., 2006). A mean can be calculated for each psychological need (6-items each for autonomy, competence, and relatedness) with a higher score representing greater satisfaction of that need. The scale will be adapted by replacing "exercise" with "physical activity".

Social Support: Social support will be measured using a modified version of Sallis' social support questionnaire (Sallis et al., 1987). The 7-item survey uses a 6-point Likert-type scale and assesses emotional support (3 items) and practical support (4 items). A similar version has been used in a similar intervention among individuals living with SCI and is sensitive to change in physical activity behaviour (Ma et al., 2019).

The Treatment Self-Regulation for Exercise Scale (TSRES): The TSRES assesses autonomous and controlled motivation. The 15-item TSRES uses a 7-point Likert scale ranging from 1 (not at all true) to 7 (very true) to assess why one *would* engage in exercise activities (Levesque et al., 2007). The scale will be adapted by replacing "exercise" with "physical activity".

The Determinants of Physical Activity Questionnaire (DPAQ): This 33-item questionnaire is derived from Taylor et al. (2013) and based on the components of the Theoretical Domains Framework (Michie et al., 2008). This questionnaire aims to understand the behaviour change factors that influence LTPA among ambulators with SCI. A modified version will be used to assess the following domains targeted in the intervention: Knowledge, Beliefs about Capabilities, Skills, Social Influences, Beliefs about Consequences, Action Planning, Coping Planning, and Goal Conflict (24-items).

Action Control: Action control will be assessed with six items that ask participants to indicate the extent to which they self-monitor their physical activity (1 = definitely false; 7 = definitely true) (Sniehotta et al., 2005). The scale has been demonstrated to be valid and reliable in individuals living with SCI. The scale will be adapted by replacing "exercise" with "physical activity".

The Leisure-Time Physical Activity Questionnaire-SCI (LTPAQ-SCI): The LTPAQ-SCI is a self-report recall measure administered by the student investigator to understand the frequency, duration, and intensity of LTPA performed over the previous seven days (Martin Ginis et al., 2012).

The Measure of Experiential Aspects of Participation (MeEAP): The MeEAP is a questionnaire to assess the six experiential aspects of participation (i.e., belongingness, meaning, mastery, engagement, challenge, and autonomy) across life domains (Caron et al., 2019). The

MeEAP is completed separately for each life domain with 12-items. Participants will be asked to complete the MeEAP for the exercise and sport domains only, for a total 24 items. Participants respond using a 7-point Likert type scale ranging from 1 (strongly disagree) and 7 (strongly agree).

The Craig Handicap Assessment and Reporting Technique – Short Form (CHART-SF): The CHART-SF will be used to assess employment and financial resources (Whiteneck et al., 1992). This questionnaire allows for both multiple choice and fill-in-the-blank answers. The CHART-SF will be modified to 2-items for the current study to only assess employment hours and financial earnings.

Acceptability

Semi-Structured Interview: After the final measurements at 8-weeks, participants from the intervention group will be invited to participate in an interview. This interview will allow the participant to provide feedback on the intervention with respect to satisfaction, burden, usability, and recommendations for future improvement. Previous interventions report high levels of satisfaction (Brawley et al., 2013), usability, and acceptability (Allin et al., 2020).

3. RESEARCH DESIGN/PROTOCOL

This randomized controlled trial will examine the feasibility and acceptability of a mHealth application called Stronger Together. Stronger Together is an app that hosts programs for individuals with chronic illnesses and disabilities. In this study, we are developing and testing the Stronger Together program that aims to improve the quantity and quality of physical activity among ambulators with SCI. Furthermore, the study will also collect pilot data on the magnitude of the effects on physical activity participation (quality and quantity) and psychosocial influences on physical activity. Individuals living with SCI who walk and live in Canada, or the United States will be recruited for this study and will be assigned to either a wait-list control or intervention group. The wait-list control group will be instructed to maintain their current health habits and that we would prefer them to not to engage in any new physical activity programs for the next 8-weeks. This is to ensure that potential program effects are independent of any other physical activity program, which is a standard protocol among physical activity randomized controlled trials. The wait-list control group will be invited to access the intervention after 8-weeks.

Potential participants will be immediately directed to complete the consent forms/baseline measures in Qualtrics. Once consent and baseline measures are completed, participants will be randomized into either the wait-list control or intervention condition. We will aim to recruit at least 8-10 participants with consent and baseline measures completed before randomization into conditions in order for there to be enough participants in the program at the same time for peer support. After the first 8-10 participants, we will randomize individuals immediately after baseline testing so that individuals randomized to the intervention group can join others in the app right away. Randomization will be done by Dr. Kathleen Martin Ginis using a random numbers generator in blocks of 2 and 4 with even groups in each condition (i.e., n=10 per condition). Waitlist-control participants will be directed to continue their normal daily activity.

Intervention participants will be directed to the App store to download the Stronger Together app to proceed with app registration. Participants will then be connected with the community coach who is a 'real live person' who monitors in-app activity (this will be the program lead, SL). Other in-app features include peer discussion groups, behavioural support, and educational modules to support strategies to increase the quantity and quality of physical activity.

The 8-week program features weekly blocks of content. Each week builds from the previous week and targets specific components related to the three basic psychological needs (autonomy, relatedness, competence). The overall cadence of each weekly block is maintained throughout. For example, each week contains: 1) education modules 2) a worksheet or guided practice to apply the strategies in their own goals for that week along with embedded questions to discuss with their community coach 3) behavioural support from the community coach and 4) peer support from the discussion group. Participants in the intervention group will be encouraged to use the app as often as needed (but at least once per week) and actively participate in the programming. The community coach (SL) will prompt participants who have not engaged in the app in a week to remind them to complete weekly modules. In-app data, including user metrics will be collected and analyzed for descriptive patterns and assess correlations with the outcome measures (e.g., is the amount of time spent in-app correlated with changes in behaviour).

Participants in both the intervention and control groups will be asked to participate in eight online questionnaires provided through the survey platform Qualtrics at three different time points (baseline/onboarding, 4- and 8-weeks of using the Stronger Together program). A link to these questionnaires which will be hosted on Qualtrics will be emailed to all participants. Participants in both groups will also complete a 5-minute demographic questionnaire at the beginning (baseline) of the study. Outcome measure included in the online surveys will include the following: basic psychological needs (The Psychological Need Satisfaction in Exercise Scale); autonomous and controlled motivation (The Treatment Self-Regulation for Exercise Scale); social support (Sallis et al., 1987); action control (Sniehotta et al., 2005); behaviour change constructs (Determinants of Physical Activity Questionnaire); leisure-time physical activity (LTPAQ-SCI); quality participation (MeEAP); and employment (CHART-SF).

After completing the final online survey (at 8-weeks), participants in the intervention group will be invited to participate in an interview to further explore their experiences and to increase our understanding of factors that influence acceptability and satisfaction of the Stronger Together program. The interview will be structured whereby the participant will go through the application with the interviewer to discuss components that they liked and disliked. This will provide a greater understanding of user engagement. Interviews will take place through video conferencing software. The interviews will be audio recorded to transcribe and code for analyses. The interviewer will confirm their consent verbally at the start of the interview.

Additionally, feasibility metrics will be kept and recorded by the program lead (SL) throughout the duration of the study. These metrics are related to process, resource, management, and scientific feasibility. More information on the feasibility metrics can be found in the research proposal (Appendix A).

4. RECRUITMENT

Inclusion Criteria
Potential participants will be selected for the study if they:

- Can read and write in English
- Own a smartphone or tablet
- Are 19 years of age or older
- Are a Canadian or United States resident
- Have sustained a spinal cord injury
- Are greater than 1 year post spinal cord injury
- Walk for their daily mode of mobility (do not use a wheelchair for daily mode of mobility)

This study will attempt to recruit a total of 20 individuals with SCI who ambulate in Canada or the United States. Recruitment will happen through open channels such as social media and word of mouth. The program lead (SL) will approach eligible groups that may be interested in the program through email and social media channels (i.e., Instagram, Facebook, Twitter) using the recruitment letter and/or poster. Community organizations that have members who have expressed interest in participating in SCI research studies will be emailed. These organizations will provide postings and communications through newsletters, postings on Facebook, and emails to members. Dr. Kathleen Martin Ginis is affiliated with community organizations whom will be contacted. Information about the study will also be posted to the International Collaboration on Repair Discoveries (iCORD) community newsletter and website for recruitment.

Individuals who identify themselves as potential participants will be directed to complete an online consent and enrolment form via Qualtrics. This form details the inclusion and exclusion criteria for participants. Eligible participants will then receive an email from Qualtrics on behalf of the program regarding the next steps and how to download the app to get started. Once participants have joined the Stronger Together platform on their smartphone, they will be guided through an onboarding procedure, and connected with the community coach. Other in-app features include peer discussion groups, behavioural support, and educational modules to support strategies to increase the quantity and quality of physical activity.

5. REMUNERATION

Participants will be incentivized to complete questionnaires through compensation. Participants can receive up to $100 for partaking in this study if they complete all questionnaires and the interview. Participants will be compensated for completing questionnaires at each time point: $20 at time 1 (baseline), $30 at time 2 (week 4), and $40 at time 3 (week 8). If participants complete all questionnaires at all time points, they will receive $90. If they partake in the interview, they will receive an additional $10.

6. ADVERSE EVENTS

We do not think there is anything in the study that could harm or be bad for the participants. However, the following may happen in the study: Questionnaires, interview and intervention

programming: Occasionally, answering questions about feelings and experiences may make participants feel uncomfortable. Participants are not required to answer all of the questions and may skip any that make them feel uncomfortable or bring up any of their concerns. Participants that do experience an emotional reaction (e.g., distress) during programming, surveys or interviews will receive a list of resources that they may access (e.g., for mental health concerns). There is also a live coach who monitors the app and can respond directly to participants who have concerns.

It is possible that the actions taken to achieve set goals (as encouraged by the weekly content) may lead to an adverse event (e.g., a fall during walking that results in a fracture, if increased walking was something that the participant wanted to do). During the consent process, participants will be advised that if such a situation occurs to receive medical attention and to report such instances to the project coordinator. Additionally, during the consent process, individuals will be advised that information provided by the health coach should not be prioritized over advice given by their health professionals, and that if they have such concerns that this should be raised with the health coach, and if not resolved then with the project coordinator.

7. POTENTIAL BENEFITS

The Stronger Together program may have the potential to improve physical activity and related health behaviours and may reduce the risks of developing a chronic disease or underlying health issue. The program may also improve self-management strategies, as it represents a low-cost, easily mobilized, and proactive approach to ensure positive physical activity participation among ambulators with spinal cord injury, especially during the COVID-19 pandemic. The information we gather will also be of benefit to people organizing leisure-time physical activity programs for people living with spinal cord injuries and for other people in the future who will participate.

8. DATA ANALYSIS

Demographic information will be used to describe the sample. Descriptive statistics will be used to characterize the sample using means and standard deviations for continuous variables and proportions and frequencies for categorical variables. Mixed effects models will be used to test for statistically significant different ($p<0.05$) in quantitative outcomes. Qualitative interviews will be transcribed, and a content analysis of the interview transcripts will be guided by an inductive approach

9. CONFIDENTIALITY

All electronic files will be saved in a password protected folder on UBC's One Drive. All electronic files and devices containing personal information about an identifiable individual collected for the purposes of this study will be encrypted. All data that is downloaded from the password-protected Qualtrics survey platform will be entered into processing (e.g. excel) and statistical software (SPSS). These electronic files will be saved in a password-protected folder on UBC's One Drive. The contact information for each participant will be stored in

the master participant file database, only accessible by the study PI, co-investigators and study staff. This file will be password-protected and saved in a password-protected folder on UBC's One Drive in a separate location from the data files. This contact information will not be linked to files that contain responses to the study outcomes.

Interviews will occur over UBC licensed Zoom and the servers for these are located in Canada. Digital audio recordings of interviews will be transferred to a secure file storage in a password-protected folder on UBC's One Drive. Once transferred, the recording will immediately be deleted from the computer on which the recording was made. Recordings will be deleted once the interview transcripts have been checked for accuracy and anonymized.

The Stronger Together platform is privacy and regulatory compliant. More information about Curatio's privacy policy can be found here: https://www.curatio.me/privacy. The following statement is copied from Curatio's privacy notice: Curatio uses service providers located in Canada and countries other than Canada, including the United States, to deliver Stronger Together. These other countries may have different privacy laws than Canada and your personal information may not be as well protected as it is under Canadian privacy law. In the US, data is subject to the US Patriot Act. We have updated the letter of information and consent form to include a clickable link that directs them to Curatio's full privacy notice through this link which they can access before consenting to study participation. Participants also have the right to withdraw themselves from the study should they feel their personal information is unsafe.

The information collected at registration is the user's email, password and user/display name. The researchers would not have the ability to remove the information. The information is owned and governed by the users themselves.

The consent forms and questionnaires will be administered via Qualtrics. Qualtrics is a cloud-based service contracted by UBC. The survey information collected using this tool is stored in Toronto, Ontario and backed up in Montreal, Quebec.

All data will be accessible via Curatio and Qualtrics. This data will be patient-provided (e.g. email address, name - if chosen to provide in app). This data will not be identifiable, unless the patient chooses to disclose/share their personal information. We will inform participants that they can sign up with their email address and choose a display name that is not connected to themselves (pseudonym), and also choose not to provide any more personal information about themselves. Data from questionnaire responses will be tied to the user's profile in the app in order to connect any changes in their responses to their in app activity. However, data from the questionnaires and the in app activity data will be stored using a participant ID that is not connected to any of their personal information shared in app.

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