UC San Diego

Office of IRB Administration (OIA)
Biomedical Protocol for
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Dance – Randomized Control Trial

Protocol Number: 812643

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Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale
All		

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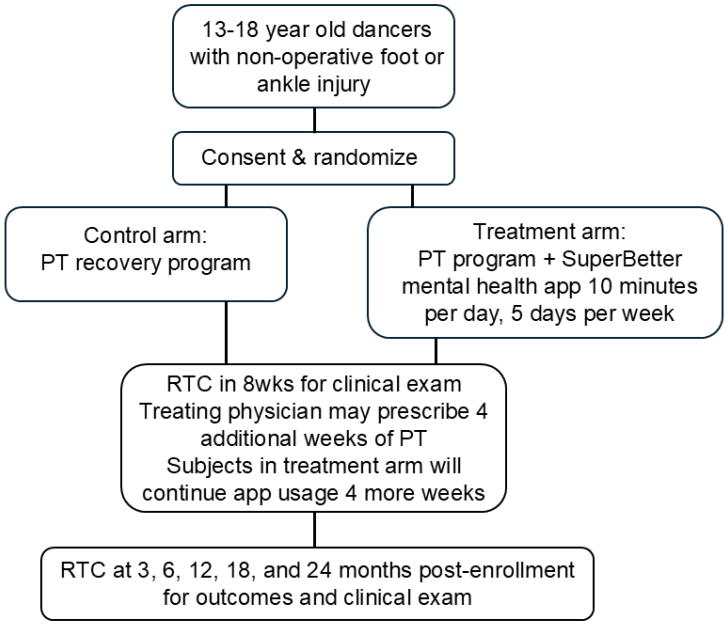
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Dance – Randomized Controlled Trial
Study Description:	This project aims to enhance self-compassion in adolescent dancers recovering from a foot and ankle injury by incorporating the use of a mental health intervention app using gamified design during their recovery.
Objectives:	*Primary Objective:* To assess rates of return to dance without limitations after start of non-operative treatment in dancers recovering from foot and ankle injuries *Secondary Objectives:* 1) To assess self-compassion in the recovering dancer during and after the nonoperative treatment of their foot and ankle injury 2) To assess musculoskeletal function during and after the recovery process
Endpoints:	*Primary Endpoint:* Return to dance after treatment of injury *Secondary Endpoints:* 1) Self Compassion (SCS) scores collected at 3, 6, 12, 18, and 24 months 2) Foot and Ankle Ability Measure (FAAM) and Patient-Reported Outcome Measurement Information System (PROMIS)
Study Population:	13-18 year old dancers
Phase:	Not applicable – not a drug trial
Description of Sites/Facilities Enrolling Participants:	Rady Children's Hospital, San Diego
Description of Study Intervention:	Qualifying participants will all be placed in a physical therapy recovery program for their injury and randomized into treatment or control group for implementation of the gamification mental health app to use during their recovery path. Outcomes scores for pain, physical function and emotional distress will be collected at the time of enrollment, 3 months, 6 months, 12 months, 18 months and 24 months after the start of treatment.
Study Duration:	4 years
Participant Duration:	2 years

1.2 SCHEMA


13-18 year old dancers with non-operative foot or ankle injury
Consent & randomize
Control arm: PT recovery program
Treatment arm: PT program + SuperBetter mental health app 10 minutes per day, 5 days per week
RTC in 8wks for clinical exam
Treating physician may prescribe 4 additional weeks of PT
Subjects in treatment arm will continue app usage 4 more weeks
RTC at 3, 6, 12, 18, and 24 months post-enrollment for outcomes and clinical exam

1.3 SCHEDULE OF ACTIVITIES (SOA)

Procedures	Enro	8 we	3 mo	6 mo	1 ye	18 m	2 ye
Informed consent	X						
Demographics	X						
Medical History	X						
Randomization	X						
Physical Exam	X	X	X	X	X	X	X
Outcomes Scores	X		X	X	X	X	X
Standard PT activities	X	X	X*				
App intervention (treatment group only)	X	X	X				

*= Additional PT up to 12 weeks/3months may or may not be ordered by the treating physician for both the treatment group and observation group depending on the recovery of the subject's foot and/or ankle injury

2 INTRODUCTION

2.1 STUDY RATIONALE

A dance injury can create psychological distress (11). We aim to explore the effect on return to dance, recurrence of injury and mental health during and after treatment of dance injury via the use of a mental health intervention. Low self-compassion specifically has been linked to psychological distress in athletes which can impair the recovery process during injury (21). This is an unexplored area in the dance population, which we aim to examine through this study. The gamified mental health app SuperBetter has been shown to have a positive and comparable effect on anxiety and depression scores when compared with group Cognitive Behavioral Therapy (CBT) interventions (5). We do not currently have the resources to administer group CBT interventions and therefore are using the gamified app as a proxy. It has also been shown to be an effective intervention with improved outcomes in treatment of adolescent concussion patients (1). Its use has not been explored in adolescent athletes. Thus, this project aims to enhance self-compassion in adolescent dancers recovering from a non-operative foot

and ankle injury by using a gamification mental health app to augment the physical therapy and home exercise program during the recovery course.

2.2 BACKGROUND

There is a noticeable disparity in the amount of research focusing on mental health and injury prevention in athletics versus dance, particularly when it comes to available interventions for use during the recovery process. In athletics, numerous studies examine mental health issues like depression and anxiety, with well-developed injury prevention strategies. These studies often feature well-designed, prospective research. In contrast, dance-related studies on mental health are fewer, with a lack of applied interventions, and a predominant focus on young adult dancers. Injury prevention in dance is less explored, with some studies highlighting risk factors but calling for more research on mental and preventive strategies. Overall, athletics outside of dance has a more extensive body of research, while dance still needs more comprehensive studies, particularly in the application of mental health interventions. The SuperBetter app was created by Jane McGonigal to address psychological symptoms that affected her during recovery from a serious concussion (23). A study in 2021 looked at the efficacy of app usage for mental health and demonstrated efficacy in improving anxiety and depression for the SuperBetter app (22). We plan to use it as a proxy to traditional CBT and explore the association between direct mental health intervention and the indirect effect on self-compassion during injury recovery in this study.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Use of the gamification app requires use of an electronic device which could increase screen time use in developing adolescents. The use of the app would be limited to no more than 15 minutes daily and would be discussed with guardians prior to implementation. Patients who do not have access to a smart phone or tablet may not be able to participate in the study. Patients may experience boredom or fatigue with the app and/or study questionnaires. Though unlikely, subjects may experience emotional discomfort or distress from the content of the app and/or study questionnaires. While the questionnaires do not ask about specific, potentially traumatic experiences, broadly being asked about feelings such as depression and compassion for oneself may feel uncomfortable for some. To avoid this risk, we will verbalize during enrollment that subjects may skip any questions they wish should any make them feel uncomfortable. The only additional risk to participants involved in the trial is potential loss of confidentiality. All measures to ensure patient confidentiality will be employed, including password protection of research files and devices, locked access to the research cabinet, coding of data with separate storage of the key and coded data, and restricted access limited to those who have a need to know for performance of their responsibilities.

2.3.2 KNOWN POTENTIAL BENEFITS

Use of the SuperBetter app offers mental health benefits using a gamification design which has been shown to be an effective mental health intervention and also allows asynchronous intervention, preventing missed school and extra medical visits that would be required for virtual or in-person mental

health interventions (5). As such, use of the app may serve as a tool within the ongoing shortage of mental health resources.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Many older children/adolescents are using technology (computers, smart phones, tablets) for school and personal reasons, therefore the investigators do not feel use of this app would add significantly to the overall screen time for each individual patient, therefore the theoretical risks to the patient are low and the potential benefit high.

Numerous studies have investigated mental health in athletics, yet mental health in dancers is understudied. We believe through utilizing minimal-risk questionnaires about mental health and physical function, as well as implementing this mental health intervention, may help shed light on an important knowledge gap for this population and their recovery from injuries, including return to dance.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To assess rates of return to dance without limitations after start of non-operative treatment in dancers recovering from foot and ankle injuries	*Return to dance after treatment of injury*	*Investigators want to see the immediate effect of the mental health app on short-term recovery and return to dance, but also the longer lasting effects (if present) after injury recovery.*
Secondary		
To assess self-compassion in the recovering dancer during and after the nonoperative treatment of their foot and ankle injury *To assess musculoskeletal function during and after the recovery process*	*FAAM, PROMIS, and Self Compassion scores collected at 3, 6, 12, 18, and 24 months*	*Investigators want to see the immediate effect of the mental health app on short-term recovery and return to dance, but also the longer lasting effects (if present) after injury recovery.*
Tertiary/Exploratory		
None		

4 STUDY DESIGN

4.1 OVERALL DESIGN

Null hypothesis (H_0): There will be no difference in self compassion scores to return to unrestricted dance at 3 months between the mental health app group and control group.

Alternative hypothesis (H_1): Self compassion and return to unrestricted dance is expected to be improved in the mental health app treatment group compared to control group.

Patient Enrollment and Randomization: Patients who meet inclusion criteria at this single site will be offered enrollment in this RCT. Enrolled patients will be randomized into one of 2 groups. It will be true randomization without patient preference but will not be blinded. There are no sub-studies or stratifications to be performed within this group.

Trial Interventions: Following randomization, the control group will undergo physical therapy treatment only while the experimental group will also participate in mental health exercises through the app, SuperBetter, for approximately 10 minutes 5 days per week for 12 weeks. All participants will have a minimum order of 8 weeks of physical therapy. At 8 weeks, depending on the individual patient and injury, the doctor may order an additional 4 weeks of PT, for a total of 12. This will be according to the physician's standard of care for their practice and clinical expertise. The number of PT visits ultimately attended by each subject will be recorded. If those in the treatment arm are not prescribed 4 additional weeks of PT at the 8-week time period, they will still use the app for 4 additional weeks for a total of 12 weeks of app usage.

Data collection: All patients in both groups will return to clinic at 3 months, 6 months, 12 months, 18 months, and 24 months. The 24-month visit represents completion of participation in the study. Throughout the trial, patients will be monitored for safe usage and engagement with the mobile app, to determine if they need to stop or limit the intervention.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

The current study utilizes 2 groups, where one is treated with the intervention of the mental health app in addition to PT, and the other group only participates in SOC PT alone, as we are trying to see whether adding the mental health app component plays a role in improving rates of return to dance and recovery.

4.3 JUSTIFICATION FOR DOSE

Dosage of the SuperBetter mental health app will be 10 minutes, 5 days per week, for 12 weeks. The 10 minute length of the exercise is predetermined by the app. 5 days per week is the recommended frequency of app usage, which came from a 2021 study which showed 10 minutes per day, 5 days per week was effective to offer support to individuals with mild-to-moderate depression and anxiety symptoms, and be a possible, alternative solution for those who cannot attend in-person therapeutic sessions (22).

4.4 END OF STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed all phases of the study including the last visit or the last scheduled procedure shown in the Schedule of Activities (SoA), Section 1.3.

The end of the study is defined as completion of the last visit or procedure shown in the SoA in the trial globally.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of informed consent (adult participant), or consent of parent/legal guardian in conjunction with adolescent assent (minor participant)
2. 13 to 18 years of age
3. Endorses dance as their primary sport, or participates 3 days per week or greater in dance prior to injury
4. Stated willingness to comply with all study procedures including the intervention regimen and availability for the duration of the study
5. Access to a device with which the SuperBetter app can be downloaded and used

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Dance is not a primary sport or less than 3 days per week spent dancing prior to injury (skater, gymnast, other sport)
2. Requiring surgery or prior surgery for the injury being treated
3. Injury outside of the leg below the knee
4. Known eating disorder or bone density issue (documented abnormal Z score and/or eating disorder diagnosis upon review of the medical chart)
5. Verbalized plans to not return to dance after recovery from the injury

5.3 LIFESTYLE CONSIDERATIONS

Not applicable.

5.4 SCREEN FAILURES

Potential subjects will not be consented for this study unless they meet all of the inclusion criteria. Subjects that are enrolled in the study but are later determined to meet exclusion criteria will be considered screen failures and will be removed from the study and the reason for their removal will be documented.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

The study intervention will be mental health exercises via the SuperBetter app for dancers participating in PT rehab for foot or ankle injuries. The control will be PT rehab only, without implementation of the SuperBetter app.

Subjects who enroll and are randomized into the treatment arm will be assisted in clinic to log into the app SuperBetter. They will be added to the group run by the "host"/study staff. The SuperBetter app offers a daily exercise on a schedule that will be managed by the "host" or study staff. Subject will complete 1 full activity per day. This activity will not exceed 15 minutes in total including app boot-up, but the full activity itself will not exceed 10. These activities ask participants to practice different exercises that might be found in Cognitive Behavioral Therapy, such as mindfulness. They are framed like a game for engagement, where the subject can "get a power up" when they take 30 seconds to breathe deeply and think of 3 loved ones, as an example. 1 full daily activity is constituted by 4 to 6 very brief activities similar to the previously described.

Both groups will undergo physical exams at their normally scheduled orthopedic appointments at baseline, 8 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months where presence/absence of reinjury, return to dance, adherence to PT and/or the SuperBetter app, type(s) of dance, and hours of dance per week will be assessed. Both groups will be asked to complete the PROMIS, SCS, and FAAM at baseline, 3-, 6-, 12-, 18-, and 24 months.

6.1.2 DOSING AND ADMINISTRATION

All subjects will receive an initial PT order for 8 weeks. The treating physician may order an additional 4 weeks of PT depending on the individual patient and injury. Total number of attended PT appointments for each patient will be recorded. Subjects randomized into the treatment group will undergo mental health exercises 5 days per week, approximately 10 minutes per day, for 12 weeks alongside their 8 or 12 weeks of normally scheduled PT appointments. They will practice these exercises on a mobile device via the SuperBetter app. Those randomized into the control group will also participate in a physical therapy treatment program for 8 weeks or 12 weeks with no utilization of the SuperBetter app.

6.2 PREPARATION/HANDLING/STORAGE/ACCOUNTABILITY

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6.2.1 ACQUISITION AND ACCOUNTABILITY

Not applicable, as our project utilizes a mobile app rather than a physical product or device. It will be readily accessible by downloading from the app store.

6.2.2 FORMULATION, APPEARANCE, PACKAGING, AND LABELING

Not applicable.

6.2.3 PRODUCT STORAGE AND STABILITY

Not applicable.

6.2.4 PREPARATION

Study staff will assist in downloading and accessing the SuperBetter app for those patients in the treatment arm. The application goes through an introductory training with the participant prior to completing their first exercise. This introductory training will consist of instructions for using the app and will be done at the participant's home.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Patients who meet inclusion criteria at this single site will be offered enrollment in this RCT. Enrolled patients will be randomized into one of 2 groups. It will be true randomization without patient preference but will not be blinded. There are no sub-studies or stratifications to be performed within this group.

6.4 STUDY INTERVENTION COMPLIANCE

Email reminders will be sent through the app by the study team to remind the subject to complete their exercise(s). Subjects in the study group will be asked if they have been participating in the app usage and/or PT exercises prescribed at their clinic visits. The study staff will serve as a "host," and new treatment arm participants will be added to a group that is managed by the "host"/study staff. The host account has the capability to see whether a participant has completed daily exercise(s) or not. Noncompliance will be determined as a subject not registering in the app, or not using the app at all. If a subject is using the app less than prescribed, they will still be included but we will make note of their number of activities completed and will verbally inquire about their app usage at their following clinic visit.

6.5 CONCOMITANT THERAPY

Not applicable.

6.5.1 RESCUE MEDICINE

Not applicable.

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION

Discontinuation from the SuperBetter exercises does not mean discontinuation from the study, and remaining study procedures should be completed as indicated by the study protocol. If a clinically significant finding is identified (including, but not limited to changes from baseline) after enrollment, the investigator or qualified designee will determine if any change in participant management is needed. Any new clinically relevant finding will be reported as an adverse event (AE).

The data to be collected at the time of study intervention discontinuation will include the following:

- Clinical exam
- Outcomes (FAAM, PROMIS, SCS)
- Type of dance
- Hours of dance per week
- Number of PT sessions completed
- Duration of time in PT from start to finish
- Type of injury
- Amount of PT done prior to enrollment
- Repeat and new injuries
- Full return to dance (only if discontinuing past 12 weeks)
- Persistent pain with dance (only if discontinuing past 12 weeks)
- Additional treatment

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Failure to follow up
- Change of mind regarding randomization
- Significant study intervention non-compliance, defined as not registering in or using the app once
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- Disease progression which requires discontinuation of the study intervention
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded on the enrollment log. Research participants who sign the informed consent form and are randomized or are not randomized will be replaced.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to return for the 24 month visit and is unable to be contacted by the study site staff.

The following actions must be taken if a participant fails to return to the clinic for a required study visit:

- The site will attempt to contact the participant and reschedule the missed visit within 10 days and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record or study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 EFFICACY ASSESSMENTS

- **Physical examination (all visits)**
  - Presence/absence of reinjury
  - Return to Dance status
  - Adherence to PT and/or SuperBetter app exercises
  - Type of dance
  - Hours of dance per week
- **Administration of questionnaires (all visits)**
  - PROMIS + PROMIS mental health
  - SCS
  - FAAM

The **Self Compassion Scale (SCS)** is a validated measure of self-compassion in individuals, which is a concept or trait associated with psychological wellbeing including, potentially, lower depression and anxiety (7). It asks patients questions about their self-kindness or, conversely, self-judgment during everyday times of difficulty. We will be using the short form version which has been shown to be an economical alternative to the long Self Compassion Scale, saving time for subjects by reducing the length of the questionnaire by half, while still being reliable (16). This survey will take approximately 5 minutes to complete.

The **Foot and Ankle Ability Measure (FAAM)** is a validated measure of physical function for a broad range of musculoskeletal conditions of the lower leg, foot, and ankle (17). It asks patients questions about their current level of difficulty performing different everyday tasks, activities, and sports motions. This survey will take no more than 10 minutes to complete.

The **Patient-Reported Outcomes Measurement Information System (PROMIS)** is an effective measure seen to be useful in evaluating pain interference in diverse settings, and mental health among musculoskeletal patients (19,20). It asks questions regarding patients' pain interference with activity and daily living, mobility, and current depression and anxiety symptoms. This survey will take no more than 10 minutes to complete.

8.2 SAFETY AND OTHER ASSESSMENTS

Subjects will be assigned exercises within the app by the "host," which will be managed by the study staff. One activity will be released per day. They will only be sent 5 per week. To mitigate any potential fatigue, discomfort, or distress from the app usage, or questionnaires, we will inform participants that they may leave any survey question blank that they do not wish to answer, and to communicate with us should they feel they need to stop using the app at any time.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS (AE)

The FDA definition of an Adverse event is any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

The following guidelines will be used to describe severity of AEs:

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".]

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study

intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.

- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

There are no expected adverse events.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The Principal Investigator will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

Since this study is applying mental health exercises, there are not potential adverse events as there may be in an experimental drug study. Any complications that arise, such as emotional distress from the app or questionnaires, will be documented in the study database and in the subject's medical record and will be treated according to standard of care. There may be a remote possibility that an unforeseen adverse event could occur which would be reported to the IRB.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

As this is a minimal-risk study in healthy children, and there is no study drug or device, SAEs are not expected. However, should an SAE occur, it would be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable. It will be reported to the IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

Families will be notified of any SAEs, including, but not limited to, emotional distress or discomfort as a result of the questionnaires and/or app and that if that occurs they should reach out to their clinical care team.

8.3.8 EVENTS OF SPECIAL INTEREST

Not applicable

8.3.9 REPORTING OF PREGNANCY

Not applicable

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the Data Coordinating Center (DCC)/lead principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;

- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB within 48 hours of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 10 days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 10 days of the IRB's receipt of the report of the problem from the investigator.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

Participants in this study will be informed of UPs by one of the physicians working on the study.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s):
  - Null Hypothesis (H_0): There will be no difference in self compassion scores to return to unrestricted dance at 3 months between the mental health app group and control group.
  - Alternative Hypothesis (H_1): Self compassion and return to unrestricted dance is expected to be improved in the mental health app treatment group compared to control group.
  - Type of Comparison: Superiority
  - Time Point: 12 months
  - Analysis Method: Logistic regression or Fisher's exact test depending on data distribution.
- Secondary Efficacy Endpoint(s):
  - Change in Self-Compassion Scale scores over time (repeated measures ANOVA or nonparametric equivalent) in experimental group compared to control group
  - Association of self-compassion with FAAM and PROMIS scores (correlation/regression)
  - Time to initial return to dance (Kaplan-Meier with log-rank test or Cox regression)
  - Reinjury incidence (descriptive comparison by self-compassion group)

9.2 SAMPLE SIZE DETERMINATION

Planned Sample Size and Feasibility
The total number of participants planned for enrollment is 50, which includes a buffer to account for expected attrition.

Outcome Measure Used for Sample Size Calculations
Return to unrestricted dance participation at 12 months, a binary (yes/no) outcome.

Test Statistic
A Fisher's exact test will be used to compare the proportion of participants who return to unrestricted dance between experimental and control groups (dichotomized by a median split or similar method).

Statistical Hypotheses
Null Hypothesis (H_o): There will be no difference in self compassion scores to return to unrestricted dance at 3 months between the mental health app group and control group.
Alternative Hypothesis (H_1): Self compassion and return to unrestricted dance is expected to be improved in the mental health app treatment group compared to control group.

Assumptions for Sample Size Calculation
- Alpha (Type I error rate): 0.05 (two-tailed)
- Power (1 - Beta): 0.80 (80%)
- Effect Size: Odds Ratio (OR) = 5.0
- Expected Proportions:
    - Control group: 60% expected to return to dance
    - Experimental: 95% expected to return to dance
- These assumptions are informed by preliminary data and theoretical rationale suggesting that higher self-compassion is strongly associated with better emotional regulation, adherence to rehabilitation, and psychological resilience—all of which plausibly contribute to better recovery outcomes in dancers (Zarzycki et al., Gennarelli et al., Christino et al).

Statistical Method and Software
- Sample size was calculated using:
    - Validated using G*Power 3.1 (Faul et al. 2007)
- Using these assumptions, the required sample size is:
    - 38 participants total (19 per group) to detect an OR of 5.0 with 80% power at $\alpha = 0.05$.
- Missing data on the primary endpoint (i.e., return to dance status at 12 months) will be minimized through close follow-up and contact strategies. If missing data occur, analyses will proceed using available-case analysis and sensitivity analyses will be conducted as described in Sections 9.4.2 and 9.4.3.
- Interim Analyses
    - No formal interim analyses are planned due to the small sample size and short duration of primary outcome measurement. Therefore, no statistical correction (e.g., O'Brien-Fleming or Pocock boundaries) is required.
- Sensitivity and Robustness Checks
    - Given the small sample size and reliance on a relatively large assumed effect size (OR = 5.0), the robustness of the sample size was tested under varying assumptions:

Control Group Return Rate (p_1)	**Experimental Group Return Rate (p_2)**	**Effect Size (OR)**	**Required n per group**	**Total Sample Size**

60%	95%	12.7	19	38
60%	90%	6.0	26	52
60%	85%	4.25	33	66

- This supports the feasibility of the current design to detect large effects, while highlighting that smaller effects will not be statistically detectable in this study.
-

9.3 POPULATIONS FOR ANALYSES

- Intent-to-Treat (ITT): All participants who initiate treatment
- Per-Protocol (PP): Participants with full follow-up data and ≥80% adherence to recovery protocol
- Safety Population: All participants (reporting adverse events and reinjury)
- Exploratory Subgroups: Participants may be stratified into tertiles or above/below median self-compassion for exploratory comparisons

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

- Descriptive statistics will be presented. Continuous data will be evaluated with the Shapiro-Wilk test of normality, data that is considered normal with that test will be evaluated with Levene's test of homogeneity of variances. Data that are found to be parameteric with both tests, will be treated as normally distributed and evaluated with analysis of variance (ANOVA). Continuous data that fails either test of normality listed above will be evaluated with the Mann-Whitney U. Continuous data will be presented as means ± standard deviation, with the range. Non-parameteric continuous data will include the median as well.
- Categorical data will be evaluated with Pearson's Chi-square, or Fisher's exact test. Odds ratios will be calculated for categorical data that is found to be significantly different among the two groups.
- Statistical significance will be defined as $p<0.05$.

9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

- The primary outcome of interest is return to dance (binary).
- The proportion of subjects in each group that returned to dance will be evaluated with Pearsons's chi-square or Fisher's exact test depending on the distribution of outcomes. If there is fewer than 10 subjects in any group (control that returned to dance, control that did not return to dance, experimental group that returned to dance, experimental group that did not return to dance), Fisher's exact test will be used.
- Odds ratios will be calculated and presented for significant findings.
- Subjects will be excluded if they are missing data related to our primary outcome of interest.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

- Our secondary outcomes of interest are self-compassion scale (continuous), FAAM (continuous), PROMIS (continuous).
- Normally distributed data will be evaluated with ANOVA. Nonparametric data will be evaluated with the Mann-Whitney U.
- Subjects will be excluded from analysis if they are missing secondary outcomes of interest.

9.4.4 SAFETY ANALYSES

This is not applicable to this study.

9.4.5 BASELINE DESCRIPTIVE STATISTICS

- Demographic descriptive statistics will include age at enrollment, hours of dance per week, number of physical therapy (PT) visits total, and amount of PT prior to enrollment. These continuous variables will be compared among the two groups using ANOVA or the Mann-Whitney U as described above.
- Additional demographic data that will be presented is sex, type of dance, prior treatment, whether or not the current injury is a new injury, or a repeat injury. This data will be presented as a percentage, but will not be analyzed.

9.4.6 PLANNED INTERIM ANALYSES

Not applicable.

9.4.7 SUB-GROUP ANALYSES

We are basing our sample size on our primary outcome of interest, and we do not anticipate having a large enough ample to evaluate subgroups.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will not be listed by measure and time point.

9.4.9 EXPLORATORY ANALYSES

There are no planned exploratory analyses for the study.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB) and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB and/or Food and Drug Administration (FDA).

10.1.2 CONFIDENTIALITY AND PRIVACY

Enrollment will occur in the clinic. The clinic schedule will be screened for eligible participants by age and presence of non-operative foot or ankle injury. The record of those candidates will be reviewed for presence/absence of abnormal Z score and/or prior or current diagnosis of an eating disorder, presence of either would be exclusionary. For those eligible candidates, the treating physician will confirm during appointment primary sport, which is standard of care for orthopedic injury appointments. Those otherwise eligible candidates who endorse dance as primary sport will then be considered fully eligible. During these eligible subjects' routine clinic visit, the treating physician will briefly discuss the study to gauge interest in participating. If the family expresses interest, a member of the study team will enter the exam room and directly explain the study in depth and obtain written consent and HIPAA authorization from the subject prior to data collection.

An application for a partial HIPAA waiver is being requested to identify potential study participants. Identification of subjects satisfies the four criteria for granting a waiver of consent:

a) The research activity of identifying subjects is minimal risk
    a. No data will be collected on subjects that do not meet the inclusion criteria of the study. Only the name of the subject and appointment time will be collected for subjects that do meet the inclusion criteria and those subjects will be asked to provide written consent to participate in the study. The date of birth, date of appointment, and appointment time will be discarded for subjects that do not provide written consent to participate in the study. The name and medical record number of subjects that do not wish to participate in the study will be kept with the consent log with a note indicating that the subject has been approached and does not wish to participate. This is necessary to ensure that subjects that do not wish to participate are not approached more than once. The name and medical record number of subjects that do not wish to participate in the study will be discarded once enrollment for this study is complete.
b) The waiver will not adversely affect the rights and welfare of the subjects

a. The waiver is being requested for identification purposes only and will in no way affect the rights and welfare of the subjects. All appropriate methods to ensure continued confidentiality of patients will be employed, thus we do not feel this waiver increases risk to patient rights/welfare.

c) The research activity of identifying subjects to be consented for enrollment in the study could not practicably be carried out without the waiver.
   a. We intend to collect written consent on all subjects included in this study. We would not be able to identify subjects without a waiver allowing us to identify them.

d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
   a. We do not anticipate that additional pertinent information about individual subjects will arise as a result of participation in this study.The following PHI will be collected for recruitment purposes under the waiver: Name, medical record number, date of birth, date of appointment, and time of appointment. This information is necessary both to access the patient's medical chart and to determine age at the time of enrollment. We must know the date and time of appointment in order to have research staff present and available for candidates who are potentially eligible for enrollment in the study. Access to the medical record using the name and MRN will allow us to view their record for history of documented abnormal Z score or eating disorder diagnosis, which is an exclusion criterion.

All measures to ensure patient confidentiality will be employed. Each site will enter coded data into a password-protected database on a secure server. Only the investigators and research teams at each site will have access to their own data.

10.1.3 FUTURE USE OF STORED SPECIMENS AND DATA

There are no biological specimens related to this study. While we have no current plans to share patient data, we have included in the informed consent that de-identified data may be shared for future uses in the event that this becomes desirable at a later time.

10.1.4 KEY ROLES AND STUDY GOVERNANCE

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10.1.5 SAFETY OVERSIGHT

Parents may supervise children's use of the app to ensure use within appropriate limits. Subjects' use of the app is also limited by the length of the single activity which takes approximately ten minutes only to complete. These activities will only be released once daily, 5 days per week. They will be released on a schedule set by the "host" which is the study team through the app, and will not exceed 5 days per week, for 12 weeks.

In order to join the SuperBetter app, patients will be added to a group in the app run by the "host" (study team). Name and date of birth of new participants added to the group will be coded for patient anonymity. Parent email, or patient if over the age of 18, will be required and the app may send periodic updates regarding changes to the app or collecting feedback. Some information will be automatically collected by the app including device information, approximated geolocation information, and app activity log data. App users traditionally have the option to log in using social media credentials, such as Facebook or Apple, in which case additional information may be collected. However, we will standardize to request families only log in with parent, or adult participant, email addresses to minimize additional data collected(18).

SuperBetter does not sell personal information to third parties and does not generate revenue by selling in-app advertising(18).

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10.1.6 CLINICAL MONITORING

Patients enrolled in this study are participating in a physical therapy program which is monitored for patient safety according to standard of care clinical treatment by the treating physician and athletic trainer(s) on site.

10.1.7 DATA HANDLING AND RECORD KEEPING

10.1.7.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant enrolled in the study. Data recorded in the electronic case report form (eCRF) derived from source documents should be consistent with the data recorded on the source documents.

Clinical data (including adverse events (AEs), concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into the appropriate 21 CFR Part 11-compliant data capture system provided by the Data Coordinating Center. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

10.1.7.2 STUDY RECORDS RETENTION

Study documents should be retained for a minimum of 3 years after termination of the study for departmental recordkeeping and the University of California San Diego IRB recommendations.

10.1.8 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation, or within 10 working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents and reported to the Data Coordinating Center. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

10.2 ADDITIONAL CONSIDERATIONS

None

10.3 ABBREVIATIONS

AE	Adverse Event
ANOVA	Analysis of Variance
CFR	Code of Federal Regulations
CMP	Clinical Monitoring Plan
CRF	Case Report Form
DCC	Data Coordinating Center
eCRF	Electronic Case Report Forms
FAAM	Foot and Ankle Ability Measure
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ITT	Intention-To-Treat
MOP	Manual of Procedures
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
PROMIS	Patient Reported Outcomes Measurement Information System
PT	Physical Therapy
RCT	Randomized Control Trial
RTC	Return to Clinic
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SCS	Self Compassion Scale
SMC	Safety Monitoring Committee
SOA	Schedule of Activities

SOC	Standard of Care
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A Summary of Changes table for the current amendment is located in the Protocol Title Page.

Version	Date	Description of Change	Brief Rationale

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