LONG TITLE

Abbreviated Title

Table of Contents: *These are the minimum sections that are required; depending on your project additional sections might necessary. Remember, the purpose of this document is to guide your day-to-day operations toward the successful completion of your study. It can also serve as foundation for your IRB application.*

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OBJECTIVE

Short term objective: *Briefly (1-2 sentences or phrases) describe the immediate goal of the study, for example to evaluate feasibility, or acceptability, or effectiveness, etc. The short-term objective describes what you hope to accomplish by the end of the study*.

a. To test the feasibility and effectiveness of a novel rehabilitation-based cognitive and behavioral skills program treatment for the long-term management knee osteoarthritis.

Long term objective: *OPTIONAL: Briefly (1-2 sentences or phrases) describe how the results of this study fit within the larger context of your lab, other studies, care pathways, etc.*

a. To obtain an RO1 to fully test the effectiveness of the treatment program in a larger sample and with multiple therapists using pilot data generated from the current proposal.

SPECIFIC AIMS

1. List the specific aims as written in the grant document or as provided by the investigative team
    a. State the hypothesis for each specific aim

BACKGROUND AND SIGNIFICANCE:

Provide a brief overview of the background science for your intervention and what your study will contribute. This information can either be abstracted verbatim from the grant proposal or reworded for brevity and simplicity. The goal of this section is to provide the IRB and study staff sufficient information to understand the rationale for the study.

Types of information provided in this section:

- *Scope of problem (in dollars, numbers of patients, lives, etc.)*
- *Knowledge gap*
- *Introduction to theory behind proposed intervention*

Description of proposed intervention and how it will impact care (i.e. significance)

PRELIMINARY STUDIES:

Briefly describe previous work that supports the proposed intervention. For example, similar interventions in other patient populations, different delivery mechanisms for the same intervention, etc.

METHODS

SAMPLE SIZE: *N=[insert desired sample size, meaning number of individuals that you need to complete the study]*

Be specific – understand how many people you need to finish the study relative to how many people you will screen relative to how many people you will consent.

ELIGIBILITY:

Be sure to provide operational definitions for each criterion, this information can go here or in your procedural manuals.

Inclusion Criteria

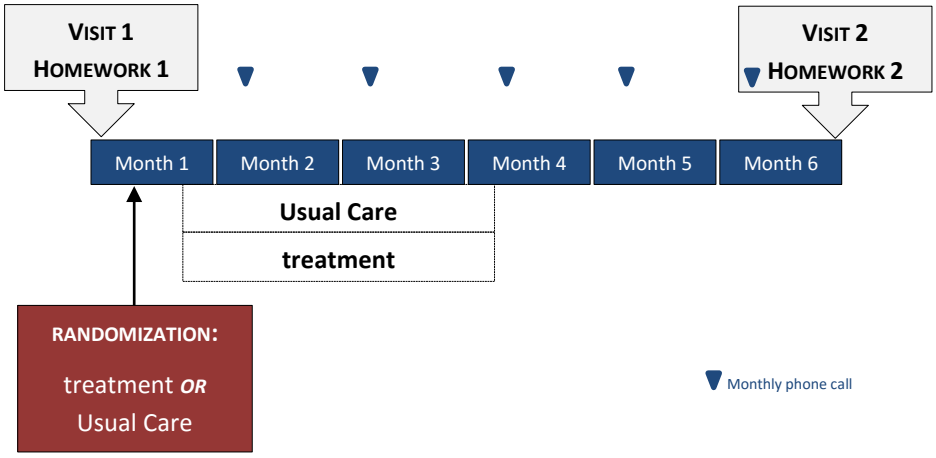
- [List all inclusion criteria]

Exclusion Criteria

- [List all exclusion criteria]

Participant Timeline: *Display the major elements of participation; timelines, tables or lists are acceptable depending upon study team choice and the needs or complexity of your study.*

EXAMPLE TIMELINE:



Research Procedures

TABLE 1. EXAMPLE LIST OF RESEARCH PROCEDURES

Procedure	Description	Occurs
6-minute walk	Walk at self-selected "usual" pace on a flat surface; total distance walked in 6-minutes is recorded.	Visits 1 and 2 Time 0 and 24wk
Surveys	Assess general health status and clinical status using self-report instruments	Visits 1 and 2 Time 0 and 24wk
In-home data collection	Waist-worn pedometer for 7 consecutive days to collect in vivo step count data; accompanying logbook used to enhance objective data.	Visits 1 and 2 Time 0 and 24wk
Treatment	Weekly series of 6 sessions with a research therapist that focuses on [*insert crux of your intervention]* to help manage [*insert disease, symptom, etc. that you want to impact*]. [*Briefly describe what each session will involve*.	Weeks 3-12
Health care use	Monthly phone calls to assess health care use and to maintain contact with the participant	Week 0, 5, 9, 13, 17, & 20

Location [*describe where the study visits and/or interventions will take place*]

EXAMPLE:

- *Study visits will occur at …*
- *Participants will complete therapy at ….*
- *Participants will complete daily logs at home…*

Description of [*insert name of intervention*]: *Describe strategies, materials, topics, how the participant will interact with interventionists or study intervention materials (i.e. calls, view videos, listen to recordings, read, etc.), delivery specifications of interventions (e.g. timing and frequency of interactions, etc.)*

Describe how the participant will progress through the intervention and any modifications that might be necessary.

Other details to include if necessary:

- *Any homework or outside work required of participant*
- *Any special equipment*
- *Qualifications of interventionists*

TABLE 2. EXAMPLE OVERVIEW OF AN 5-WEEK INTERVENTION

Session	Description of content	Participant Requirements
Session 1 [*insert name of session or module*]	[*describe what information will be conveyed during session or what will occur during session*]	[*describe specific activities or requirements of participants for each session*]
Session 2		
Session 3		
Session 4		
Session 5		
Session 6		

Strategies for Ensuring Treatment Fidelity:

List and describe all strategies for ensuring that you intervention is delivered as intended, received as intended, and used as intended (refer to Bellq AJ, et al. 2004)

Statistical Analysis

TABLE 3. EXAMPLE LIST OF STUDY VARIABLES: *A list of study variables helps promote data integrity and can help prioritize data collection*

Variable Domain	Scale used	Type of Variable
Physical Function	SF-36 v2.0	Primary Outcome
Patient Global Impression of Change	Global impression of change scale	Primary Outcome
Pain	McGill Pain Inventory, Short Form	Secondary Outcome
Fatigue	Fatigue Severity Scale	Secondary Outcome

Physical Activity	Fitbit Zip activity tracker	Secondary Outcome
Sleep Problems	Pittsburgh Sleep Quality Index	Descriptive
Depressive Symptoms	Beck Depression Inventory	Descriptive
Functional status	Timed up & go	Descriptive
Medical History	Study-specific self-report	Descriptive
Demographics	Study-specific self-report	Descriptive
Health Care Use	Study-specific self-report	Descriptive
Quadriceps Strength	Isometric knee extension from hand-held dynamometer	Descriptive

Data Analysis Plan:

List each specific aim and the analysis strategy; include the software packages used to analyze data, the statistical techniques you used, any data manipulations (centering variables, aggregating variables, etc.), and the variables of concern for each technique.

Missing Data:

Describe the expected missing data rate and any procedures you will use to manage missing data: data imputation, insertion of the mean, etc. Be sure to specify if any of your instruments have any requirements for missing data (i.e. participant only answers 5/7 questions on a survey)

For activity monitors and interventions that use devices, indicate minimum data requirements.

Indicate if there are differences between missing data and data that is missing because it wasn't applicable for a particular participant

References