University of Social Welfare & Rehabilitation Sciences

Neuromusculoskeletal Rehabilitation Research Center

<<Title of Project>>

This title should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied.

Protocol Number: <Number>

<<Name of PI>>

A Proposal SUBMITTED TO

Neuromusculoskeletal Rehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences

FOR

Postdoctoral Research Fellowship Program

1st Supervisor: Name (Affiliation)

2st Supervisor: Name (Affiliation)

Consultant: Name (Affiliation)

<Day Month Year>

CONFIDENTIALITY STATEMENT:

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the supervisor.

Contents

Short biography of principal investigator:

Abstract:

Grant Number:

<Grant Number>

Objective:

Include the primary and secondary objectives. These objectives should be the same as the objectives contained in the body of the protocol.
<Primary Objective:
Secondary Objectives: >

Methodology:

Provide a short description of the protocol, including a brief statement of the study hypothesis(es). This should be only a few sentences in length.

Description of Study Intervention/Experimental Manipulation:

…

Study Population:

Specify the sample size, gender, age, demographic group, general health status, and geographic location.

Research Design:

…

Study setting:

…

Endpoints:

Include the primary and secondary endpoints. These endpoints should be the same as the endpoints contained in the body of the protocol.
<Primary Endpoint:
Secondary Endpoints: >
Estimated time (in months) from when the study opens to enrollment until completion of data collection.

Population and Sampling Technique:

…

Sample Size:

…

Results:

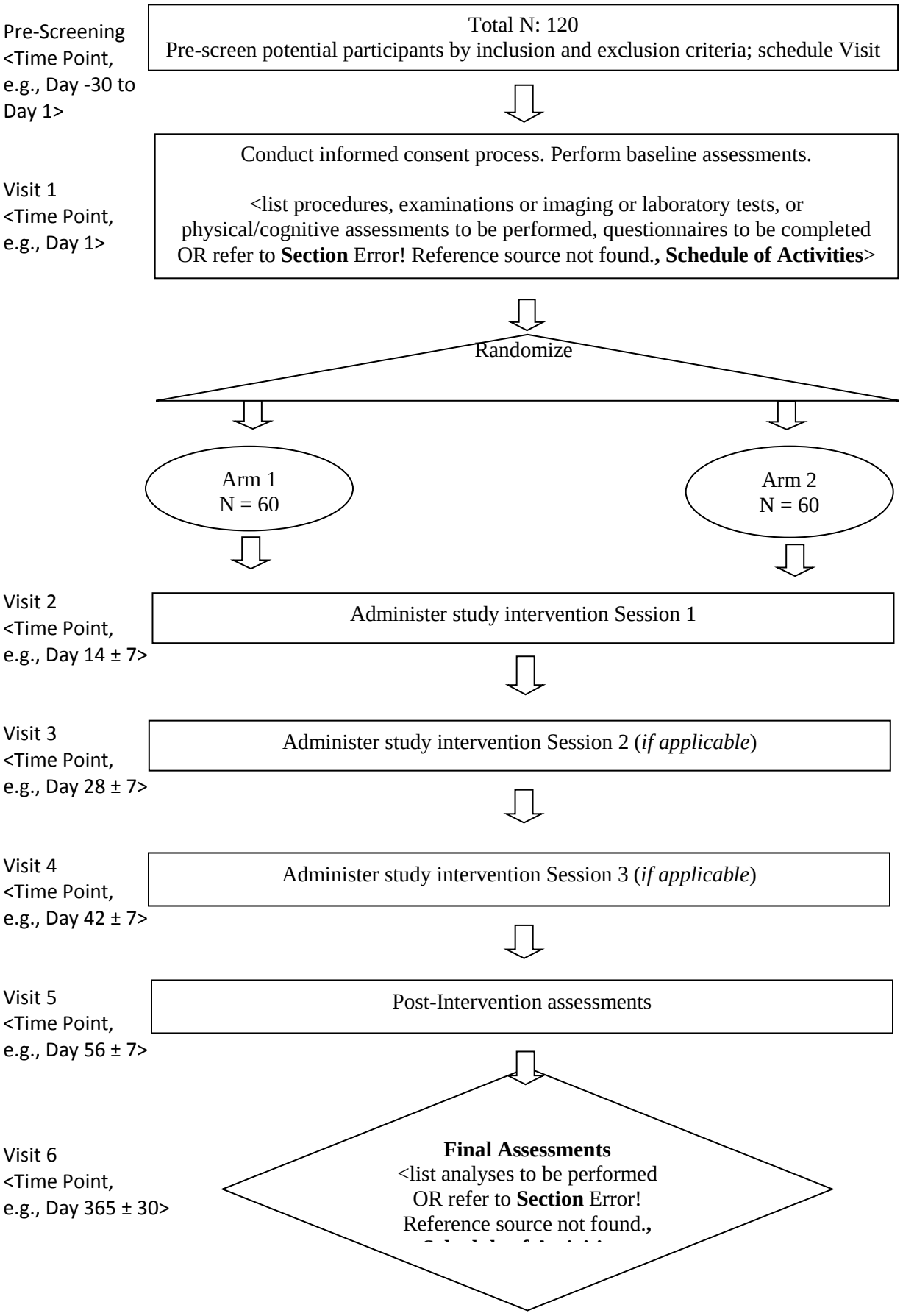
…

Keywords: …

Graphical Schema:

This section should include a diagram or flowchart that provides a quick "snapshot" of the study and ideally is limited to 1 page. Below is an example schematic that shows the level of detail needed to convey an overview of the study design. Revise with study-specific information and adapt the diagram to illustrate your study design (e.g., changing method of assignment to study group, adding study arms, visits, etc.).

Example #1 Flow Diagram *(e.g., randomized controlled trial)*



List of abbreviation:

1. Introduction

- A summary of relevant basic and clinical research, including research conducted in other countries
- Discussion of important literature and data that are relevant to the trial and that provide background for the trial (reference citations should be listed in References list)
- Applicable clinical, epidemiological, or public health background or context of the clinical trial
- Importance of the clinical trial and any relevant treatment issues or controversies

2. Literature Review:

(Maximum three pages)

3. Research Rationale

State the problem or question (e.g., describe the population, disease, current standard of care, if one exists, and limitations of knowledge or available therapy), the reason for conducting the clinical trial and the rationale underlying the intervention. State the name and the nature of the intervention, the hypothesized target(s) of the intervention (i.e., the putative cognitive, affective, behavioral, social, community, organizational, etc., target necessary to produce the behavior change relevant to the clinical outcome), and the clinical outcome of interest.

4. Research Significance

…

5. Research Questions

- Question 1
- Question 2
- Question 3
- Question 4
- …

6. Research Objective and endpoints:

Provide a description of the study objectives and endpoints, as well as a justification for selecting the particular endpoints, in the table format included below. This will provide clear articulation of how the selected primary and secondary endpoint(s) are linked to achieving the primary and secondary objectives and an explanation of why endpoint(s) were chosen. Data points collected in the study should support an objective or have a regulatory purpose. Therefore, careful consideration should be given prospectively to the amount of data needed to support the study's objectives.

An objective is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., feasibility, acceptability, engagement of the intervention target, identifying mechanisms of action, mediation, moderation, efficacy, effectiveness, dissemination, implementation).

A study endpoint is a specific measurement or observation to assess the effect of the study intervention. Study endpoints should be prioritized and should correspond to the study objectives and hypotheses being tested. Give succinct and precise definitions of the study endpoints used to address the study's primary objective and secondary objectives (e.g., specific diagnostic tests that define safety or efficacy, clinical assessments of disease status, assessments of psychosocial characteristics, patient reported outcomes, behaviors or health outcomes). A full description of study endpoints, including administration, scoring, psychometrics, adjudication of endpoints, etc., belongs in Section **Error! Reference source not found.**, Study Assessments and Procedures.

A putative mechanism of action is the theorized explanation for how the intervention functions.

Consider whether primary and secondary endpoints should be adjusted for multiple comparisons, family-wise error rates, alpha inflation, etc.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
The primary objective is the main question. This objective generally drives statistical planning for the trial (e.g.,	*The primary endpoint(s) should be clearly specified and its importance*	*Briefly identify the hypothesized role that each measure plays in the study objectives, e.g., moderator,*	*This column is optional and can be included when appropriate.*

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
calculation of the sample size to provide the appropriate power for statistical testing).	*and role in the analysis and interpretation of study results should be defined. The primary endpoint(s) is the basis for concluding that the study met its objective.* *In a trial designed to establish efficacy, a primary endpoint should measure a clinically meaningful therapeutic effect or should have demonstrated ability to predict clinical benefit.*	*mediator, causal mechanisms, covariate.*	
Secondary			
The secondary objective(s) are goals that will provide further information on the use of the intervention.	*Secondary endpoints should be clearly specified and may include, for example, endpoints related to efficacy, safety, or both. Secondary endpoints are those that may provide supportive information about the study intervention's effect on the primary endpoint or demonstrate additional effects*	*Briefly identify the hypothesized role that each measure plays in the study objectives, e.g., moderator, mediator, causal mechanisms, covariate.*	

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
	on the disease or condition. It is recommended that the list of secondary endpoints be short, because the chance of demonstrating an effect on any secondary endpoint after appropriate correction for multiple comparisons becomes increasingly small as the number of endpoints increases.		
Tertiary/Exploratory			
tiary/exploratory objective(s) serve as a basis for explaining or supporting findings of primary analyses and for suggesting further hypotheses for later research.	*If exploratory endpoints will be examined, they should be specified. Exploratory endpoints may include clinically important events that are expected to occur too infrequently to show a treatment effect or endpoints that for other reasons are thought to be less likely to show an effect but are included to explore new hypotheses.*	Briefly identify the hypothesized role that each measure plays in the study objectives, e.g., moderator, mediator, causal mechanisms, covariate.	

Null Hypothesis:

…

Alternate Hypothesis:

…

1. Operational Definition:

Item 1:

…

Item 2:

…

Item 3:

…

Item 4:

…

2. Methodology:

2.1 Sample description:

…

2.1.1 Inclusion criterion:

…

2.1.2 Exclusion criterion:

…

2.2 Research design:

…

2.3 Sampling technique:

…

2.4 Sample size:

…

2.5 Study setting:

…

2.6 Study Duration:

…

2.7 Data Collection

…

2.8 Outcome measures

Primary outcome measurements:
Secondary outcome measurements:

- Data analysis plan:
- *For descriptive statistics, describe how categorical and continuous data will be presented (e.g., percentages, means with standard deviations, median, range.*
- *For qualitative research, describe how procedural and interpretive rigor will be monitored and maintained*
- *For inferential tests, indicate the p-value and confidence intervals for statistical significance (Type I error) and whether one or two-tailed*
- *Indicate whether covariates will be pre-specified in the sections below or later in a SAP*
- *State whether checks of assumptions (e.g., normality) underlying statistical procedures will be performed and whether any corrective procedures will be applied (e.g., transformation or nonparametric tests)*

For each primary endpoint:

- *Describe how the primary endpoint is calculated, if not readily apparent*
- *Describe the scale (nominal/binary/categorical, ordinal, interval); state if it is measured as a single endpoint/summary measure or repeated measure*
- *Describe the statistical procedure(s) that will be used to analyze the primary endpoint (e.g., multiple regression, repeated measures mixed models, logistic regression, Analysis of Covariance (ANCOVA)). Describe the covariates and factors in the model. Provide a rationale for covariates and how they will be selected to achieve a parsimonious model. If the decision to specify covariates is deferred for the SAP, indicate here.*
- *For cluster-randomized or individually randomized group-treatment trials describe a) how the analyses will reflect the expected positive within-group correlation and b) how the analyses will account for any heterogeneity in that correlation that may be expected among study arms or conditions as a function of the study design*
- *If fitting a repeated measures model, describe how the variance and covariance across repeated measures will be calculated*
- *Describe how results of statistical procedure(s) will be presented (e.g., adjusted means (Least-squares means (LSMEANS)) with standard errors, odds ratios with 95% confidence intervals, prevalence rates, number-needed-to-treat)*
- *Describe details to check assumptions required for certain types of analyses (e.g., proportional hazards, transformations or, when appropriate, nonparametric tests)*
- *Describe how missing data will be handled (e.g., type of imputation technique, if any, and provide justification), and approach to handling outliers, non-adherence and lost to follow-up*
- *If there is more than one primary endpoint or more than one analysis of a particular endpoint, state the statistical adjustment used for Type I error criteria or give reasons why it was considered unnecessary*

Note if more than one endpoint: the statistical approach for endpoints with the same analytic issues can be described as a group.
For each secondary endpoint:

- *Note if analysis of secondary endpoint(s) are dependent on findings of primary endpoint*
- *Describe how each secondary endpoint is calculated, if not readily apparent*
- *Describe the scale (nominal/binary/categorical, ordinal, and interval); state if it is measured as a single endpoint/summary measure or repeated measure*
- *Describe the statistical procedure(s) that will be used to analyze the secondary endpoint (e.g., multiple regression, mediation or moderation analyses, multilevel modeling, MANOVA). Describe the covariates and*

factors in the model. Provide rationale for covariates and how they will be selected to achieve a parsimonious model. If decision to specify covariates is deferred for the SAP, indicate here.

- *Describe how results of statistical procedure(s) will be presented (e.g., adjusted means (Least- squares means (LSMEANS)) with standard errors or effect size*
- *For group- or cluster- randomized trials and individually randomized group-treatment trials, describe how the analyses will reflect the expected positive within-group correlation and how any heterogeneity in that correlation that may be expected among study arms as a function of the study design*
- *Describe details to check assumptions required for certain types of analyses (e.g., checks on assumptions of normality, transformations or, when appropriate, nonparametric tests)*
- *Describe how missing data will be handled (e.g., type of imputation technique, if any, and provide justification), and approach to handling outliers, non-adherence and lost to follow-up*
- *If there is more than one primary endpoint or more than one analysis of a particular endpoint, state the statistical adjustment used for Type I error criteria or give reasons why it was considered unnecessary*

Note if more than one endpoint: the statistical approach for endpoints with the same analytic issues can be described as a group.

Subgroup Analysis:
*Describe how the **primary endpoint(s)** will be analyzed based on age, sex, race/ethnicity or other demographic characteristic(s) or sub-populations of interest, or provide justification for why such analyses are not warranted (e.g., study intervention only for use in men or children).*

*Describe how the **secondary endpoint(s)** will be analyzed based on age, sex, race/ethnicity or other demographic characteristic(s), or provide justification for why such analyses are not warranted (e.g., study intervention only for use in men or children).*

For group- or cluster randomized trials and individually randomized group-treatment trials, describe how sub-group analyses will reflect the expected positive within-group correlation and how any heterogeneity in that correlation may be expected among study arms as a function of the study design.

2.9 Ethical Consideration:

…

3. Limitations of the study:

…

4. Specialty of investigators and their contribution:

…

5. References:

(Based on Vancouver style)

6. BUDGET

S#	ITEMS	QUANTITY	COST	TOTAL NO OF	TOTAL VISIT	
1						
2						
3						
4			1			
	GRAND TOTAL					

7. Conflict of Interest Policy:

This section should include a description of how the study will manage actual or perceived conflicts of interest.

Example text provided as a guide, customize as needed:

[The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the <specify NIH Institute or Center (IC)> has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.]

8. Publication and Data Sharing Policy:

The publication and data sharing* policies should be described in this section. For example, for a study with multiple investigators, this section might state that an Executive Committee will be responsible for developing publication procedures and resolving authorship issues. Please refer to your specific contract, grant, and/or Clinical Trials Agreements.

9. Apendix-A

14.1 QUESTIONAIRE FORM

14.1.1 Item 1

…

14.1.2 Item 2

TITLE: …

10. CONSENT FORM:

Investigator: Name

Brief information

Procedure:

Brief information

Anticipated Benefits to Subject:

You will receive direct, free of cost physical therapy treatment on participating in this study. No monetary benefits will be provided to the subjects for participating in this study.

Risk:

There is no potential risk associated with this study and this study will not produce any harm to you by participating.

Benefits:

Information through this study will help to develop better physical therapy management of chronic non specific low back pain.

Injury Statement:

During the research if you get any harm due to the result of treatment, you will be provided free of cost medical treatment.

Confidentiality:

All your data and personal information will be kept secret. Apart from the researcher no one will ever access to the data without your permission.

Voluntary Participation:

Participation in this study is completely voluntary. If you decide not to participate, there will not be any negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

The investigators may also withdraw you from participation in this research if circumstances arise which warrant doing so. The decisions may be made either to protect your health or safety.

By signing this form I am attesting that I have read and understood the information above and I freely give my consent to participate in this study.

Name of subject:_____ **Signature of Subject:**_____

Date:_____

I have explained the research to the subject, I believe that he/she understands the information described in this document and freely consents to participate.

Name of Investigator:_____ **Signature of investigator:**_____

Date:_____