הקרן הלאומית למדע
المؤسَّسة الإسرائيلية للعلوم
Israel Science Foundation

ג' באב, תשפ"ד
07 באוגוסט, 2024
מספרנו: 986/24

לכבוד
ד"ר מיכל אלבוים-גביזון, פיזיותרפיה, אוניברסיטת חיפה
ד"ר עינת שופר אנגלהרד, רווחה ובריאות, אוניברסיטת חיפה
פרופ' יורם גדרון, סיעוד, אוניברסיטת חיפה

לד"ר אלבוים-גביזון שלום רב,

הנדון: בקשתכם למענק מחקר בנושא:
<u>מודל משוכלל של נפש- גוף למניעת נפילות בזקנה: מכניזם והשפעה של מדדים פיזיקאליים ונוירופסיכולוגיים</u>

הצעת המחקר אשר הגשתם לקרן הלאומית למדע לא נכללה, לצערנו, בין ההצעות אשר זכו במענקי מחקר השנה.

מצ"ב עיקרי חוות הדעת ו/או החלטת הוועדה המקצועית.

לתשומת לבכם, החלטות הנהלת הקרן מתקבלות על סמך סיקור עמיתים ודיונים בוועדות מקצועיות. ראוי להדגיש כי הוועדה המקצועית אשר בחנה את הצעת המחקר התבססה על מכלול ההערות והציונים שהתקבלו מסוקרים חיצוניים ומחברי הוועדה שהם מומחים בתחום, ונתנה משקל, בדיוניה, רק לאותן ביקורות והערכות שהיו מקובלות עליה.

מאחר שכספי ההקצבה השנתית מחולקים עד תום, החלטות הנהלת הקרן הן סופיות ואינן ניתנות לשינוי.

אנו מאחלים לכם הצלחה בהמשך דרככם המדעית.

בכבוד רב,

ד"ר תמר יפה-מיטווך
מנכ"ל

העתק: רשות המחקר, אוניברסיטת חיפה

מוזמנים לבקר באתר קול המדע https://kolhamada.isf.org.il/ - מיזם של הקרן הלאומית למדע, המגיש מידע מדעי מחזית המדע, לציבור ולקהילה המדעית בישראל.

Reviewer No. 1

Originality & Innovation
Different modalities of physical activities, including dance, are well known to be effective in preventing falls in elderly people. The present study aims to investigate the underlying mechanisms that explain this correlation. Specifically, it seeks to assess the impact of the therapist-patient relationship, heart rate variability, level of inflammation, and frontal brain activity as potential mediators.
Although the study's proposal is intriguing, it requires further clarification regarding the possible explanations for these correlations.

Project Importance & Implications
Collecting evidence to support any fall prevention interventions for older adults is essential for positive public health implications. In light of the fact that the method proposed in the study is based on specific characteristics of the therapists (i.e., creating an empathic relationship with each participant and the physical and emotional tuning to the participant's individual needs), clarification is required regarding the possibilities of the implications of the suggested intervention in different settings in the future.

Adequacy of methods
While the measurement methods outlined in the proposal appear to address the research questions, some areas require additional clarification. Specifically, more details are needed on several indicators to ensure the robustness of the findings.
In the paragraph referring to the sample size calculation, the investigators present data about expected minimal changes (MCID) in the research variables. One of the variables on which the calculation is based is TUG, which is not presented in the proposal as a variable to be measured in the study.
Regarding the psychological indicators that may act as mediators, the researchers suggest evaluating the effect of the relationship between the therapist and the participants. However, in the scientific background, there is a possible reference to the group's influence on the psychological indicators. It might be worth considering also measuring the effect of the group activity separately from the effect of the therapist. A qualitative component may be considered to evaluate this option.
Additional detail is required regarding balance assessments. While the test procedures are explained (sets of 30 seconds with eyes open and closed), the exact variables are not specified. Although there is a sentence about COP indicators related to falls, clarification is required regarding the definition of the variables.
Regarding the muscle strength assessment test, the researchers suggest using the 5STS test. It should be noted that this test does not directly measure muscle strength but indirectly (as a functional assessment). It is also important to note regarding this index that it is measured in time and that it is a reversible variable (the lower the value, the better the result). I raise this point because later, in the description of the preliminary study, the researchers claim a significant improvement in this index following the DMT+OEP intervention program, although, as presented in Table 2, it is evident that after the intervention, there is an increase in the value of this test (from 16.5 seconds before the intervention to 17.7 after the intervention).
Regarding the neuroimmunological measures, the scientific background presented in the proposal lacks reference to the nature of the proposed indices, are they considered situational or characteristic indices? Does a one-time measurement before or after an intervention period represent a change caused by long-term intervention, or are these measures affected by momentary events?

In addition, it is not clear what will be measured in the frontal brain activity test, and thus, it is not clear how the exact effect of the intervention will be evaluated. The scientific background presented in the proposal is not extensive enough to understand the impact of the intervention on this index.
Regarding the preliminary results presented in the proposal, it is important to note that the findings are based on a small sample size. The study only involved five participants in the study group and three participants in the control group, making it difficult to draw any meaningful conclusions. The elderly population is known to be very diverse, and many factors could influence the results besides the intervention program that was being tested.
Additionally, it's worth noting that the statement in the proposal about significant differences between the two groups is inconsistent with the results shown in Table 2. While the control group did show a larger impairment on the 5STS test, no improvement was observed in the study group. Therefore, it's important to recognize the limitations of this study and not draw any definitive conclusions based on these preliminary results.

Suitability of investigators' scientific background to the project
The background of the investigators is suitable for the project.

Summary (strengths/weaknesses of the proposal)
Strengths –
Inclusion of therapist-patient relationship measurement, as well as Neuroimmunological measures that may suggest underlying mechanisms for the DMT intervention.
Weaknesses –
The scientific background does not clearly explain the rationale for using the neuroimmunological indices (especially concerning brain activity). There are also no sufficient explanations for the possible connection between those indices and preventing falls.
There is a lack of measurement of the effect of group activity on preventing falls as a possible psychological factor (aside from the therapist-patient relationship).

Reviewer No. 2

This proposal is interesting, with a novel model regarding fall prevention in older adults. There are interesting measures to explore including heart rate variability and inflammation. It is not clear whether the methods will result in findings that make clear connections proposed in the model, and the study is trying to do everything at once. The methods have several limitations: the samples are small, the intervention is short in duration, with multiple variables and measurement times. It would seem that some small studies building strong links between some of the novel components, like heart rate variability and inflammatory markers with falls, would be stronger than jumping to small RCTs that may not be powered to show differences in all these variables. At best, this could be interesting as more pilot work to explore some of the variables. Some examples of limitations are noted below.

- There is no power analysis. Are any of the measures powered to show change? This may not be a big enough sample to do a mediation analysis or structural equation modeling.
- Studies suggest at least 50 hours of exercise are needed to show fall prevention effects, and OEM should be longer in duration.
- There is little rationale for the follow-up lengths- you could end up spending a lot of effort following up with participants with such a small sample, and it might not be worth it other than to show you can keep people participating in the study for that long.
- While the proposal is short, probably because of the application requirements, it is not clear what the dance intervention actually is (there are many possibilities) and how this or a dance intervention is more of a mind-body intervention than other fall prevention movement programs such as yoga, or T'ai chi.
- The empathetic therapist is not likely to show anything. If you think this is important, then you would train the intervention therapists to be empathetic so there should be no comparison.
- Strong theoretical models of behavior change are rarely applied since adherence is mentioned as a major outcome.

Reviewer No. 3

1) Originality & innovation

- The plan to examine the underlying mechanisms that may explain the intervention's effects is innovative in the context of falls research.
- Other mind-body interventions (e.g., tai chi) have been found to be effective in reducing falls and fear of falling. A discussion of other mind-body interventions, including what is known about their mechanisms with regard to physiologic measures proposed for the present project (e.g., heart rate variability, inflammation, frontal lobe function) would strengthen the proposal.
- A clearer explanation of the relationship between heart rate variability (HRV) and falls would strengthen the proposal. It is unclear why higher HRV would increase the risk of falls, when for other conditions, it is lower HRV that confers increased risk.

2) Project importance and contribution to scientific knowledge

- Even if the Mind-Body Model is effective, how it would be sustained is unclear. Psychotherapeutic interventions are typically not funded by health insurance, and so this would also have the potential to introduce health inequity if only those who could afford to pay out of pocket were able to access the intervention.

3) Adequacy of methods

- The rationale for the 2nd randomized controlled trial RCT is unclear. Why could the data that the investigators propose to collect in that RCT not be collected in the 1st RCT? This would have economies of scale and also allow for a shorter, more efficient project.
- The Dance Movement Therapy (DMT) intervention is not described with sufficient detail to understand how it will be implemented in the context of the experimental group (DMP+OEP).
- The tool to be used to assess the outcome of fall risk has not to my knowledge been tested for its responsiveness and thus may not capture any changes that may occur as a result of the intervention.
- The intent of RCT 1 appears to be a superiority trial – i.e., the underlying hypothesis to be tested is that the DMP+OEP intervention is more effective than OEP alone. It's unclear that the statistical methods as proposed are suitable for a superiority trial.
- The description of preliminary studies needs some clarification. First, what is the response option format and interpretation of responses for the single-item question regarding Fear of Falling. Second, in Table 2, it appears that the groups were imbalanced at baseline and furthermore, that the 5STS worsened on post-testing, in both arms, which is counter-intuitive. These observations need to be addressed in the analysis (i.e., how have baseline imbalances been addressed analytically?) and described in the interpretation of findings.
- Based on information in the Personnel section of the project budget, it sounds as if the research assistants who will be conducting research procedures will also serve as the interventionists. This approach may introduce bias and threaten the internal validity of study findings.
- It's unclear how the intervention, due to its nature, could be double-blinded (as per the Justification for requested Personnel in the project budget).

4) Suitability of investigators' scientific background to the project

- The investigative team is interdisciplinary, with each individual bringing relevant clinical expertise and published prior research that supports the present proposal.

5) Summary (strengths / weaknesses of the proposal)

This is overall a readable proposal proposing an innovative trial (RCT #1) that needs further honing to document what is known about other mind-body interventions (namely tai chi), justify the need for the 2nd RCT, and to ensure that all scientific methods employed are sound.