


# Effects of combined physical and cognitive program performed in socially enriched environment on older people's cognitive abilities and quality of life (StimCoAPS): study protocol for a randomized controlled trial

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## ABSTRACT

The number of older people worldwide is constantly increasing. However, ageing is accompanied by a decline in cognitive ability that can affect quality of life. Cognitive, physical and social activities can all slow this decline but social factors and their contribution to the well-being remain under-researched. The aim of this study is to analyse how the practice environment can foster these social relations and thus enhance well-being and to identify the psychological dimensions that are activated by social relations. This study is a 3-year randomised controlled trial designed to assess the effects on participants' cognitive abilities and quality of life of a combined (ie, physical and cognitive) training programme in different social practice environments. A total of 159 older people (≥65 years old) will be recruited and randomly assigned to one of three practice environments: individual practice at home (n=53), group practice in a gymnasium (n=53) and group practice in an enriched environment (n=53). All participants will complete 12-week combined training sessions and will be assessed four times: before the start, in the middle, at the end and 6 months after the end of the programme. They will undergo cognitive function (episodic memory and executive functions), physical capacity (aerobic fitness, muscle strength and dynamic balance) and psychosocial assessments (indicators of psychological well-being, social support, self-esteem, anxiety, depression and achievement goal strategies), as well as semistructured interviews. Statistical analyses will be conducted to assess the effect of the practice environment on the perceived benefits of this programme in terms of cognitive abilities and quality of life, and to determine the role of psychosocial factors in this relationship.

This protocol has been approved by an institutional review board (CERSTAPS: IRB00012476-2022-20-01-146). Trials registration number: NCT05721508.

## INTRODUCTION

The ageing of the population is generating major societal challenges, particularly in terms of public health. The question of the

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The simultaneous performance of physical exercises and cognitive activities (ie, combined training) attenuates cognitive decline in ageing and is more beneficial in a social context.

### WHAT THIS STUDY ADDS

⇒ To our knowledge, this is the first randomised controlled trial in humans to study the effects of an enriched environment, defined in the literature as featuring three types of stimuli: physical, cognitive and social.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study focuses on theoretical and practical actions, and proposes alternative ways of challenging cognitive decline in order to contribute to the quality of life of the elderly.

autonomy of seniors and their ability to remain in their own home is crucial, both for their well-being and the economy. One of the main problems associated with ageing is cognitive decline, which affects essential daily functions such as memory, attention and executive functions that can affect the quality of life of seniors.<sup>1</sup>

Several factors influencing cognitive health have been highlighted in the literature, including cognitive exercise, physical activity and social interactions. Studies have shown the benefits of either cognitive stimulation<sup>2</sup> or physical activity<sup>3</sup> mainly on memory and executive functions, but training sessions combining the two have been found to have the greatest impact on the cognition of older people.<sup>4</sup> However, some studies show mixed

results regarding combined exercise, and do not highlight the superior beneficial effect of the combined intervention compared with an individual intervention.<sup>5</sup> An important question regarding combined training is the mode of simultaneous (cognitive and physical training performed during the same session) or sequential (cognitive and physical training performed on separate days) designs. Gheysen *et al* reported a better effect of simultaneous combined training compared with sequential training. In contrast, Gavelin *et al* showed no additional effect of simultaneous combined training compared with sequential training. However, they recognised that simultaneous combined training was more feasible intervention for preserving health, because in their study, for comparable effectiveness, the dose of simultaneous training was lower than that of sequential training.<sup>5</sup> More and more research suggests that social interactions may also help prevent cognitive decline, and may even positively affect cognition and quality of life.<sup>6</sup> In the recent Rieker *et al*'s meta-analysis, they showed that the benefits of combined training are moderated by various factors such as social context. They indicated that group practice is more beneficial than individual practice, especially when training is conducted in small groups of less than 10 people.<sup>7</sup>

Environmental enrichment is a concept that has its origins in the work that Donald Hebb conducted with animals, principally in mouse models. In research dating back to 1947, he demonstrated the beneficial effects of cognitive (by games), physical (through miniattractions) and social (by placing them in a cage with several other animals) stimulation.<sup>8</sup> In humans, an enriched environment corresponds to cognitive and physical stimulation combined with social engagement in a positive emotional context, leading to cognitive enrichment.<sup>9</sup> Exposure to an enriched environment helps to delay cognitive decline and promotes the maintenance of autonomy in activities of daily living.<sup>9</sup> In humans, however, there has been little research on the effects of an enriched environment featuring cognitive, physical and social engagement stimuli. A few studies conducted with patients with Alzheimer's disease have reported positive effects on mood,<sup>10</sup> anxiety, apathy, quality of life and physical skills.<sup>11</sup> Environmental enrichment seems relevant means of preventing many aspects of age-related physiological and cognitive decline<sup>12</sup> and promoting healthy ageing, as recently shown in ageing animals.<sup>13</sup> Taken together, research findings highlight the influence of the social environment on the cognitive function of older people and the importance of considering non-biological (eg, social) factors, in order to understand the ageing process in general and the cognitive ageing process in particular. The aim of the present project is thus to assess and highlight the cognitive, physical and psychosocial benefits of a combined physical and cognitive training programme in a socially enriched environment in older adults and to assess the factors influencing these benefits.

## Main objectives

**Objective 1: assess relationship between practice environment and benefits of practice on cognitive abilities and perceived well-being**

The study's primary objective is to assess whether the social practice environment modifies the benefits of a combined training programme (ie, physical and cognitive activities during the same session) in terms of cognitive abilities and general quality of life. We hypothesise that group practice and a practice environment fostering social relations and interactions are more beneficial for the general and cognitive health of older people. We, therefore, expect participants' performances on the various physical, cognitive and psychosocial assessments to be better, on average, in a group practice setting and a socially enriched environment favouring social relations.

**Objective 2: assess psychosocial factors as mediators of the relationship between social practice environment and cognitive abilities and quality of life**

A second objective is to ascertain whether social factors make older people more or less sensitive to the effects of combined training on their cognitive abilities and quality of life. We predict that changes in social factors (self-esteem, perceived social support and anxiety) across the training sessions will mediate the relationship between social practice environment and the cognitive abilities and perceived quality of life of older participants. The feeling of belonging to the practice group and the social relationships developed during these activities will enhance self-esteem and perceived social support and reduce anxiety, thereby positively mediating the relationship between social practice environment and participants' cognitive abilities and perceived quality of life.

## Secondary objectives

- ▶ Establish participant profiles based on their levels of physical activity, cognitive ability and basic social resources, and assess the latter's moderating role in the relationship between the practice environment and cognitive abilities and quality of life.
- ▶ Conduct a 6-month follow-up to assess changes in cognitive abilities (stable, deteriorated or improved) based on the participants' adherence to new activities after the end of the 12-week programme.

## METHODS AND ANALYSIS

StimCoAPS ('Stimulation cognitive, activité physique et promotion du lien social au bénéfice de la qualité de vie des personnes âgées' (cognitive stimulation, physical activity and promotion of social relations for the benefit of older people's quality of life)) is a randomised controlled trial designed to examine the effects of combined physical and cognitive activity on general quality of life (physical, social and psychological well-being) and cognitive health, particularly in older people, in three different social practice environments: (1) individual practice at home (limited social interactions), (2) traditional group practice (gymnasium; moderated social

interactions) and (3) group practice in an enriched environment fostering social relations (high social interactions). It tests the hypothesis that the practice of combined activities in a collective setting is particularly beneficial, as it promotes social relations and interactions. We expect both cognitive performance and perceived well-being to be better after group practice in an enriched environment fostering social relations and interactions compared with traditional group practice and even more so compared with individual practice where social interactions are limited. The final aim of this study is to promote the enriched environment.

### Procedure overview

The aim is to recruit 159 older participants between January 2022 and June 2024. Several recruitment periods will be planned over the course of the project, with two periods per year (one at the beginning of the year and one mid-year). The goal will be to recruit participants by cohort for each period. In this way, five successive cohorts of participants will be established over the 3 years of the project. People within each independent cohort will have the same start and end date, whatever the assignment condition (at home, gymnasium or enriched environment). Participants will undergo the same experimental protocol, that is, a training programme combining physical and cognitive activities, with two 1-hour sessions per week over a period of 12 weeks. Moreover, each participant will undergo four assessments, before, during (at 6 weeks) and immediately after the 12-week programme, as well as 6 months after the end of the programme. Participants will be randomly assigned to one of the three social practice environments: (1) individual practice at home (limited social interactions), (2) group practice in a traditional group environment (gymnasium; moderated social interactions) and (3) group practice in an enriched environment fostering social relations (high social interactions). The randomisation will be computer generated, based on an Excel file and performed using permuted three blocks corresponding to the three conditions (at home, gymnasium, enriched environment). In each of the collective conditions, participants will undergo the training sessions in groups of 7–10 people. Enrichment will take the form of support from the training provider (Les Ateliers Cord'âges or La Vie la Santé), along with the social interactions, often intergenerational and inter-pathological, that take place during the sessions.

### Inclusion and exclusion criteria

Participants will be recruited by various means (distribution of flyers, advertisements in local newspapers, intervention in neighbourhood houses, etc). To be included, people must be at least 65 years old, independent (able to get around on their own: car, bus, walking) and living in the community (not in an institution such as a nursing home). The persons recruited must have a score on the Montreal Cognitive Assessment of at least 18.<sup>14</sup> People with contraindications for engaging in regular physical activity or who have been diagnosed with severe neurological and psychological disorders

during the last 6 months preceding the recruitment are not eligible for inclusion in this study.

### Intervention

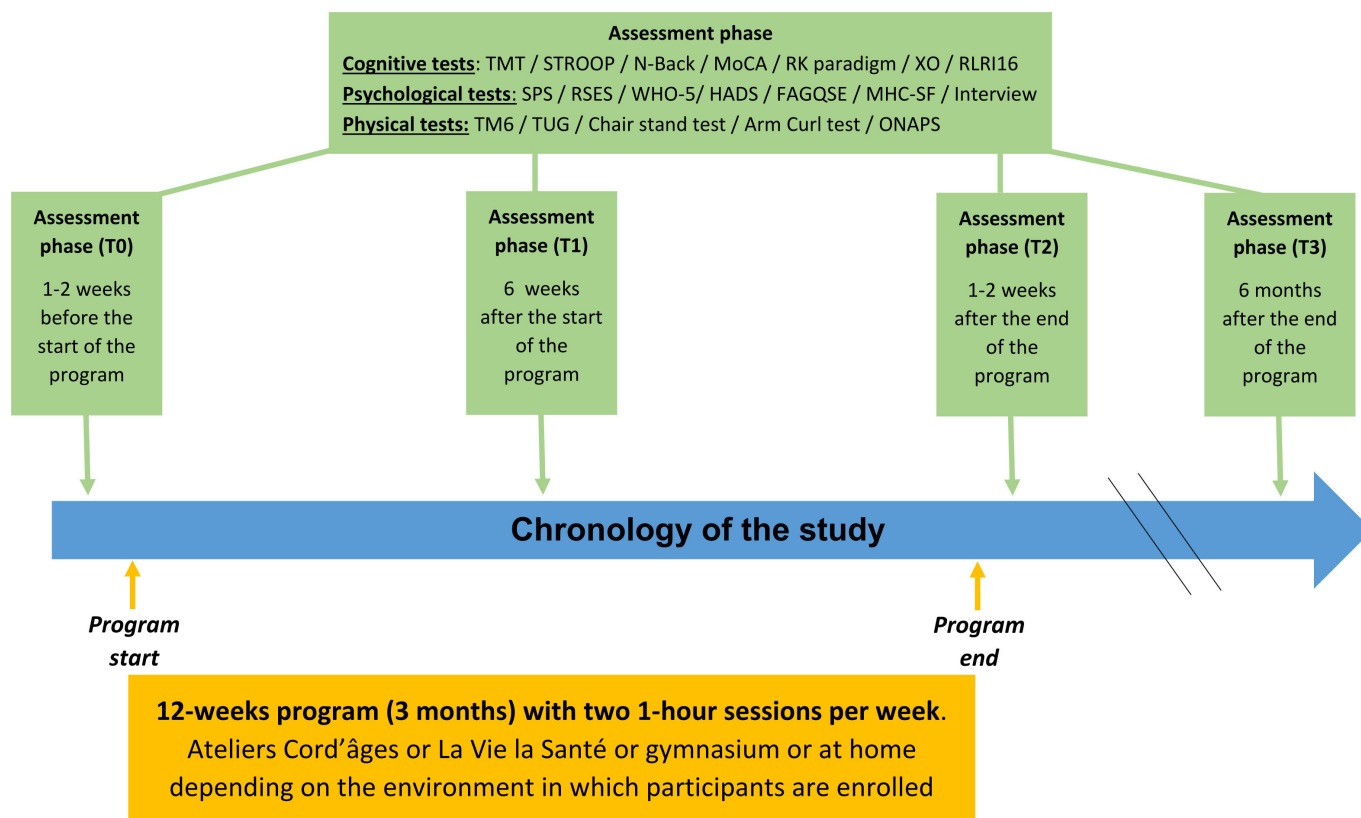
#### Twelve weeks combined exercise programme

Participants will attend a 12-week supervised combined exercise intervention programme with 2-weekly sessions (N=24 training sessions). Each training session will combine physical and cognitive activities, and be delivered by adapted physical activity teachers. More specifically, during each session, participants will practice both physical (strength, balance, coordination, mobility, endurance) and cognitive (memory, cognitive flexibility, processing speed, inhibition) exercises. A detailed presentation of the programme is available as online supplemental material. Each session will be divided into three parts: warm-up exercises for 10 min, followed by 45 min of simultaneous physical and cognitive exercises, and finally a 5 min return to calm, for a total duration of 1 hour. The sessions will be identical regardless of the condition (at home, gymnasium, enriched environment), that is, all participants will do the same activities for the same amount of time with the same equipment. The sessions will be simply adapted for individual or group practice. In group sessions, the sessions will be based on cooperation with activities performed in pairs. The types of social interactions will be different between the home condition (social interactions only subject trainer) and the group conditions in gymnasium and enriched environment (social interactions subject trainer and also subject subject). The sessions will be of light to moderate intensity. Intensity will be monitored a posteriori by objectively measuring the participants' heart rate during some sessions using a connected watch, and subjectively by assessing the perception of effort during each session using the Borg scale.<sup>15</sup> Each participant's attendance will be recorded in a register taken by the teacher at the start of each session. All participants must have attended at least 80% of the sessions (minimum of 20 sessions) to be retained in the study. Participants below this level will be excluded from the study.

### Enriched environment

The environment in this condition will be enriched by the spatial environment, as well as by the support that is available and the philosophy of solidarity that drives the two training providers (Les Ateliers Cord'âges and La Vie La Santé). These providers both adopt an approach based on the mobilisation of the individual participant's resources and the interactions between participants within the enriched environment. Their aim is to provide health and well-being education, to make people responsible for their own health.

- ▶ Les Ateliers Cord'âges is a non-profit structure that welcomes people of all ages (especially older people) who find themselves in a situation of isolation and/or vulnerability. Its objective is to break this isolation, create social relations, allow users to rebuild a social and cultural life, and reduce social inequalities. It organises leisure and stimulation activities such as



**Figure 1** Study flow diagram of the StimCoAPS study. StimCoAPS, Stimulation cognitive, activité physique et promotion du lien social au bénéfice de la qualité de vie des personnes âgées. FAGQSE: French Achievement Goals Questionnaire for Sport and Exercise; HADS: Hospital Anxiety and Depression Scale; MHC-SF: Mental Health Continuum Short Form; MoCA: Montreal Cognitive Assessment; ONAPS National observatory of physical activity and sedentary lifestyle questionnaire; RLRI16: 16-item Free and Cued Recall; RSES: Rosenberg's Self-Esteem Scale; TMT: Trail making test; TM6: Six Minutes' Walk Test; TUG: time Up and go; SPS: Social Provisions Scale; STROOP: Stroop task; XO: XO letter comparison test.

adapted sports, relaxation, dance, games, creative arts, cooking and music, and provides opportunities for exchange and sharing. Its alternative humanistic approach is based on the conviction that people's development depends in large part on the way they are looked at, envisioned or perceived.

- La Vie La Santé is a department of Poitiers University Hospital. This innovative health promotion platform aims to develop or maintain participants' good health, whether they are patients or the caregivers of people with chronic diseases. It offers an unconditional welcome and runs group workshops promoting different aspects of health (adapted physical activity, nutrition, environmental health, emotion and stress management, social health, sexual health and daily life health). Its approach focuses on the factors that promote health and well-being (physical, mental, social and psychological).

### Assessment sessions

Figure 1 shows the chronology of the study, as well as the four assessment times, before (T0), during (T1; at 6 weeks/12 sessions), and immediately after the 12-week intervention programme (T2), as well as 6 months after the end of the programme (T3). Inclusion will be preceded by an initial information meeting not shown

in this figure. The main aim of this meeting will be to inform participants about the study, give them the information sheet, and make sure they meet the inclusion criteria. Following this meeting, volunteers who meet the criteria will be included in the study. At T0, participants will be asked to sign an informed consent form. They will then begin the first of the four identical assessments. Each assessment will probe participants' cognitive, physical and psychosocial abilities. A rotation system will allow the tests to be randomised. Participants will be brought together for a half-day to complete the physical, cognitive and psychosocial assessments. The cognitive tests will be performed individually with one experimenter, while the semistructured interview will take place with another experimenter. Participants will complete the psychosocial questionnaires on their own. The physical tests will be performed at the end of the assessment, to avoid a fatigue effect that could affect performance on the cognitive tests. The assessments will be conducted by experimenters who are not involved in supervising the programme, and who are, therefore, blind to the conditions. However, participants will be informed about the different conditions of the project but not of the

**Table 1** Cognitive test battery used in the study

Cognitive tests			
Test	Duration (min)	Domaine assessed	Authors
1 Trail Making Test parts A and B	3	Flexibility	Reitan <sup>17</sup>
2 Stroop task	3	Inhibition	Stroop <sup>18</sup>
3 N-Back task	5	Working memory updating	Kirchner <sup>19</sup>
4 Montreal Cognitive Assessment	15	Basic cognitive functions	Nasreddine <i>et al</i> <sup>14</sup>
5 Mill-Hill Vocabulary Test (first assessment only)	15	Crystallised intelligence	Deltour <sup>20</sup>
6 XO letter comparison test	1	Processing-speed of information	Salthouse <sup>21</sup>
7 Remember-Know paradigm	Encoding: 2 Retention: 10 Free recall: 2 Recognition: 5	Episodic memory	Gardiner <sup>22</sup>
8 16-item Free and Cued Recall	Encoding, immediate free and cued recall, and recognition: 20 min Retention: 20 min Free and cued recall delayed: 3 min	Episodic memory	Grober and Buschke <sup>23</sup>

hypotheses, so they are not blind to the different arms of the study. All the assessments will take place in the laboratory.

### Test battery

The same battery of cognitive, physical and psychosocial tests will be used for all participants, regardless of the condition to which they are randomly assigned at study inclusion. All the tests and questionnaires we will use are validated and commonly used in research protocols. The instructions for these tests will be the usual ones.

### Cognitive test battery

The cognitive test battery (table 1) will comprise six simple cognitive tests assessing, among others, executive functions

(inhibition, planning, flexibility and working memory updating), episodic memory and processing-speed of information. These assessments will be carried out individually with the experimenter for a total duration of about 75 min.

### Psychosocial test battery

The psychosocial test battery (table 2) will comprise five questionnaires assessing different notions of self-esteem, achievement motivation goals, psychological well-being and perceived social support. During this assessment session ( $\approx$  75 min), participants will also undergo a semi-structured interview with an experimenter, to obtain qualitative data on their social life and perceived quality of life.

**Table 2** Psychosocial test battery used in the study

Psychosocial tests			
Test	Duration (min)	Domaine assessed	Authors
1 Social Provisions Scale	10	Perceived social support (attachment, social integration, confirmation of one's value, material help, orientation)	Caron <sup>24</sup>
2 Rosenberg's Self-Esteem Scale	10	Perceived self-esteem	Rosenberg <i>et al</i> <sup>25</sup>
3 French Achievement Goals Questionnaire for Sport and Exercise	10	Achievement motivation goals	Riou <i>et al</i> <sup>26</sup>
4 5-item WHO well-being index	2	Perceived well-being	Boini and Langevin <sup>27</sup>
5 Mental Health Continuum Short Form	10	Perceived well-being: emotional, social and psychological	Keyes <i>et al</i> <sup>28</sup>
6 Hospital Anxiety and Depression Scale	10	Anxiety and depression	Zigmond and Snaitth <sup>29</sup>
7 Semistructured interview	10–15	Assessment of social and cultural life, and assessment of interactions and relations with group members or teachers: 'How would you describe your social and cultural life now?', 'How the sessions with the other members of the group going?'	

**Table 3** Physical test battery used in the study

Physical tests				
Test	Duration (min)	Domain assessed	Authors	
1	National observatory of physical activity and sedentary lifestyle questionnaire (ONAPS)	10	Level of physical activity and sedentary lifestyle	Charles <i>et al</i> <sup>30</sup>
2	Time Up and Go	1	Dynamic balance/walking speed	Podsiadlo and Richardson <sup>31</sup>
3	30s Chair Stand Test (Senior Fitness Test)	1	Lower body strength	Rikli and Jones <sup>32</sup>
4	Arm Curl Test (Senior Fitness Test)	1	Upper body strength	Rikli and Jones <sup>32</sup>
5	Six min Walk Test	6	Aerobic capacity	Rikli and Jones <sup>32</sup>

### Physical test battery

The physical test battery (table 3) will consist of four simple physical tests to assess ( $\approx 20$  min) aerobic endurance capacity, upper and lower limb muscle strength, and balance.

### Sample size

The estimate of the number of participants needed for the study was based on the effect size of the combined physical and cognitive training practice on global cognition. Gheysen *et al*<sup>4</sup> conducted a meta-analysis of the effect of combined practice on global cognition according to practice condition (simultaneous or sequential) and found an effect size of  $d=0.385$  for simultaneous combined practice. Using this effect size, and with the error rate set at  $\alpha=0.05$  and power set at  $\beta=0.80$ , the power analysis from the SPSS (IBM SPSS Statistics V.27.0) software indicated that a sample size of 132 participants (44 participants per condition) would be sufficient to detect the critical effects of the conditions and their potential interactions. The power analysis was calculated from a power test analysis of variance (ANOVA): repeated measures, within-between interaction with a  $4 \times 3$  model (four repeated measures and three conditions). As this is an interventional study, we increased the sample size by 20% to take account of possible drop outs, thus increasing our sample size to 159 participants (ie, 53 in each condition).

### Statistical analysis

To meet the first objective, which is to assess the effect of the practice environment on the perceived benefits of combined training on the various cognitive (episodic memory and executive functions), psychosocial (well-being and motivation) and physical composite scores, we will conduct a 4 (time : before (T0) versus during (T1, at 6 weeks/12 sessions) versus immediately after the 12-week intervention programme (T2) versus as well as 6 months after the end of the programme (T3)) $\times 3$  (conditions: individual practice at home vs group practice in a traditional environment (gymnasium) vs group practice in an enriched environment foresting social relations) ANOVA. Conditions will be considered as a between-group factor and time as a within-group factor. We will apply a Bonferroni correction to all analysis results.

We will also examine the hypothetical mediating effects of psychosocial factors (self-esteem, social support and

anxiety) on the relationship between the practice environment and the benefits in terms of cognitive abilities and quality of life. To this end, we will apply Baron and Kenny's four-condition successive regression analysis approach<sup>16</sup>: (1) the independent variable (here, practice environment) must have a significant impact on the dependent variables (here, cognitive abilities and quality of life); (2) the independent variable must have a significant effect on the supposed mediating variable (here, psychosocial factors); (3) the supposed mediating variable must significantly influence the dependent variables, when the influence of the independent variable on the dependent variable is controlled; (4) the significant influence of the independent variable on the dependent variables should disappear when the effect of the mediating variable on the dependent variable is statistically controlled.

Finally, moderation analyses will be performed in the mediation model<sup>16</sup> to identify and control for individual characteristics (age, gender, physical profile, cognitive profile and social profile) liable to moderate the effects of the practice and the perceived benefits.

### CONCLUSION

Ageing is a natural and irreversible process that generates physical, cognitive and social deficits, affecting the autonomy and well-being of older people. The resulting health and care problems make ageing, particularly cognitive decline, a major societal challenge, as preserved cognitive abilities are essential for healthy ageing. Many physical and cognitive interventions have been designed, but the importance of social factors in these models appears to have been underestimated and underused. We suggest that special attention should be paid to the influence of psychosocial factors in predicting the relationship between practice environment and the quality of life and cognitive abilities of older people. The StimCoAPS project focuses on theoretical and practical actions that are potentially important for improving the care of older people and proposes alternative ways of challenging cognitive decline in order to contribute to the autonomy and well-being of older people.

## Trial status

The recruitment phase began in January 2022 and is expected to run until January 2024. A first cohort of 28 participants has already been formed, and completed the 12-week intervention programme between March and June 2022. Several other cohorts will also be formed, and all recruited participants will have completed the 12 weeks of training sessions by June 2024. The end of this study is estimated to be December 2024.

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**Contributors** The protocol was conceived and designed by members of the StimCoAPS Group. The statistical analysis plan was designed by TG, DC, CE and GB. The protocol was initially drafted by TG. Subsequent versions were reviewed by DC, CE and GB. Revisions were made by TG. The figure was drawn by GB. All members of the StimCoAPS group read and accepted the submitted version of the manuscript.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** An institutional review board (CERSTAPS) has approved the research protocol (notification no.: IRB00012476-2022-20-01-146). Informed consent is required before inclusion. Persons with direct access to the data must respect their confidentiality. All data collected during the study will be anonymised, and only the inclusion number will appear in the database. The results of this research are liable to be disseminated in conferences and published in conference proceedings and academic journal articles.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** All data relevant to the study are included in the article or uploaded as online supplemental information.

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