# +AGIL Barcelona: Integrated Care for Community-Dwelling Frail Older Adults – A pragmatic Stepped-Wedge Cluster Randomized Trial and Implementation Study Protocol.

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*Methods +AGIL Barcelona*

*Randomization*

The Step Wedge Cluster Ramdomized Trial design is particularly well suited for evaluating the implementation of the +AGIL Barcelona program across multiple PCCs in Barcelona. Each PCC serves as a cluster. Initially, all clusters will recruit control participants who receive standard care, including general recommendations for healthy aging. The clusters will then be centrally randomized to transition from the control phase to the +AGIL Barcelona intervention at regular intervals. This sequential crossover ensures that every PCC eventually receives intervention with centralized support to minimize potential bias. There are no reporting guidelines specific to SWCRTs, so the study's Statistical Analysis Plan (SAP) has been designed to be consistent with the extension to cluster randomized trials of the CONSORT 2010 document[31] and further recent suggestions for SWRCT[32].

*Sample size calculation*

The sample size calculation is based on results from previous RCTs[33] assessing the effect of MEP on physical function capacity. Accordingly, considering an initial average SPPB score of 9 out of 12 points, achieving an improvement of +1 point is clinically and statistically significant. This change has been established as a “minimal clinically meaningful” improvement[34].

Considering a variance of 3 in the SPPB, a 20% drop-out rate, accepting an alpha risk of 0.05, and a beta risk of 0.15, we need to include 396 participants (198 in the intervention group and 198 in the control group). This translates to 132 participants per PCC, with 66 in the intervention group and 66 in the control group, to detect this improvement as statistically significant.

*Data analysis*

Descriptive statistics will be presented to outline the overall characteristics of the study sample (both the intervention and control groups) in terms of frequencies and percentages for nominal or categorical variables and means and standard deviations for continuous variables. Baseline comparisons between treatment groups will be assessed using t-tests and chi-square tests to identify any potential imbalances in the group composition and characteristics.

The change in SPPB between the intervention and control groups will be compared using repeated measures ANOVA, initially in an unadjusted form and then adjusted for the main confounding factors through generalized linear models. Variance corrections will be applied to account for the clustering in different PCCs. Additionally, the time elapsed since the implementation of the intervention will be considered a potential confounding factor as its impact may vary based on the extent of implementation.

Secondary analyses will be conducted by stratifying for relevant variables such as sex, cognitive impairment, multimorbidity, and socio-economic status to explore whether the intervention's effectiveness varies across these demographics.

Benefits will be estimated using the EQ-5D quality of life questionnaire. Quality-adjusted life years (QALYs) will be obtained by combining survival and utility values and will be estimated using the area under the curve of the utility values between measurements.

Analyses will be performed using STATA v14.0 and R Studio.

**Qualitative Evaluation of the program implementation**

Additionally, we will evaluate the program implementation exploring the perceptions of frail older adults in the community and of healthcare professionals regarding adherence to and long-term maintenance of lifestyle changes introduced by the +AGIL Barcelona integrated care program. This evaluation aims to understand their experiences with the program and identify eventual proposals for improvement to ensure its sustainability over time.

To gather the necessary information for the study, we will conduct three semi-structured focus groups, each consisting of 6-8 participants, including frail older adults and professionals. Each session will last 60-90 minutes to encourage interactive discussions. Additional groups may be held until data saturation is achieved. Each session will be facilitated by a moderator and an observer to ensure effective communication. The focus groups will be conducted at the PCC, where the +AGIL program has been implemented,

following the completion of the 10 weeks of planned intervention. To ensure accuracy, each session will be recorded using at least two devices, and the recordings will subsequently be transcribed and analyzed by two researchers from an interpretive perspective. During the analysis, they will code units of meaning, categorize them, and identify thematic axes independently. Upon completion of this process, the findings will be unified through a mutual agreement on codes, categories, and themes. The analysis of these qualitative aspects will utilize ATLAS.ti software, version 9.