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The 5P program, personalized and participatory primary prevention pathway: Rational and design of a clinical trial in general practice

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ABSTRACT

The aging of the population is leading to an increase in the number of people with loss of autonomy, placing a strain on the health care system. Its prevention at early stages such as the frailty stage would allow an improvement in the quality of life of seniors while limiting health care expenses. The "Atout Age" prevention program set up by the health public authorities of Reunion Island for retired people and the new frailty assessment tools based on mathematical machine learning algorithms could improve the ambulatory care of senior citizens. At present, referral care remains hospital with comprehensive geriatric assessment and there is a lack of evidence of the effectiveness of a prevention pathway for loss of autonomy in primary care. For these reasons, the 5P program "Personalized and Participative Primary Prevention Pathway" has been started in order to obtain scientific evidence.

In this article, we present the objectives, design and first results, used in the 5P program up to the implementation of a clinical trial in general practice.

The program is articulated in 3 phases. A first phase to evaluate the acceptability of innovative screening tools for frailty. A second pilot phase evaluates the feasibility of a large-scale ambulatory clinical trial in general practice. The last phase described in this article, is a multisite, pseudo-randomized, controlled clinical trial measuring the impact of the "Atout Age" workshops on the physical performance and the quality of life of seniors compared with their usual ambulatory follow-up.

1. Background

In 2000, 6.9% of the world's population was aged 65 or older, but this proportion will triple to 22.6% by 2100 [1]. Between 2013 and 2050, the number of people aged 75 or over, which is still very low at present in Réunion, will increase fourfold [2]. This ageing of the population leads to an increase in health expenditure, which is difficult for the health care system to bear [3]. In light of this, clinicians, researchers, and policy makers agree on the need to prevent loss of autonomy [4,5], in particular by developing prevention and care pathways for the elderly [6]. The loss of autonomy is often difficult to reverse even with the implementation of rehabilitation programs [7,8]. Preventing it at an early stage could therefore be the most appropriate strategy to respond to this public health issue [4].

The frailty is a concept that has been studied for a long time, particularly in geriatrics because of the identification of a sub-population of elderly people at greater risk of pejorative health events such as unscheduled hospitalization, institutionalization, excess morbidity with secondary disability, mortality, etc. [9–12].

In metropolitan France, 45% of people over the age of 65 are considered pre-frail [13,14]. It is particularly interesting to note that it has been shown that acting on these determinants allows for the reversibility of the latter [10,15], thus reducing the risk of loss of autonomy, the evolution towards dependency and, consequently, health expenditure [13].

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Currently, the assessment, management and prevention of loss of autonomy is provided by the Comprehensive geriatric assessment (CGA). It consists of a global medical-social evaluation of the state of health of an elderly person with the implementation of a personalized care plan. It has proven its effectiveness in preventing loss of autonomy [16]. However, the CGA appears to be a time-consuming process that requires strong geriatric skills [17,18]. This makes it unlikely that CGA can be carried out outside geriatric services and limits their use by general practitioners who are the pillars of the French health care system [19].

Since the 2000s, innovative tools for measuring mobility have been available, making it possible to carry out measurements of frailty according to Fried et al. The accuracy of the motion sensors used by the "Smart Check®" device, combined with innovative mathematical approaches through machine learning, could enable early evaluation and longitudinal monitoring of frailty [20]. However, these mathematical approaches require a large amount of data in order to improve the accuracy of the algorithms [21]. In addition, ambulatory prevention interventions, such as the "Atout Age" prevention workshops created in Reunion Island, lack studies evaluating their clinical effectiveness [22]. Also, screening tools lack data to validate their diagnostic performance in discriminating stages of frailty in primary care [20,23].

These elements associated with the difficulties of setting up an ambulatory clinical trial motivated the setting up of the 5P research program "Personalized Participatory Primary Prevention Pathway".

The objective of this article is to describe the rationale, the objectives and the design of the 5P program in the prevention of loss of autonomy.

2. The 5P research program

The main objective of this interdisciplinary program is the evaluation of a personalized prevention program for the loss of autonomy among the elderly. This ranges from identifying frail people, to workshops on preventing loss of autonomy, to assessing their needs and setting up a personalized care plan.

To achieve these objectives, the 5P program was planned over 5 years from 2016 to 2021 in 3 chronological and progressive phases in order to respect the feasibility of the project while maintaining maximum methodological rigor. This article was written between phase 2 and 3 of the 5P research program and each phase is an independent study:

Phase 1 (Achieved) is an evaluation of the social acceptability of health technologies and autonomy, and in particular technological screening tools. This first stage focused on the acceptability of the various proposed workshops by seniors and the acceptability of the protocols and measurement equipment (sensors, platform) implemented.

Phase 2 (Achieved) "5P-PILOT" is a feasibility study of a large-scale ambulatory evaluation of the "Atout Age Mobility" prevention workshops using the "Smart Check®" prototype screening tool.

Phase 3 (In progress) "5P-SCALE" study is an implementation of a multi-site, ambulatory, pseudo-randomized, controlled clinical trial to measure the impact of the "Atout Age" prevention workshops and the evaluation of the "Smart Check®" ambulatory screening tool.

The primary and secondary objectives of the 5P program by phase are summarized in Table 1.

Table 1
Main objectives of the 5P program according to the phases of the project.

Phase 1	Main objective: to assess the acceptability of the screening tools used in the 5P project.
Phase 2	Main objective: 5P-PILOT study to assess the feasibility of a large-scale ambulatory evaluation of the "Atout Âge" prevention workshops using the "Smart Check®" screening tool.
Phase 3	Main objective: 5P-SCALE study: Measuring the impact of "Atout Âge" prevention workshops on seniors' physical performance and quality of life. Secondary objective: Improved detection of frailty and pre-frailty.

2.1. Phase 1: Evaluation of the social acceptability of technology screening tools

2.1.1. Phase 1: introduction

The objective of this phase was, on the one hand, to evaluate the acceptability of the prevention workshops and, on the other hand, to study the acceptability of health and autonomy technologies, in particular the innovative tools for screening frailty deployed in the framework of the 5P project. Indeed, one of the anticipated risks was that the technological tools would be considered too intrusive and therefore not accepted by the population or by professional users. Similarly, since the inclusions for phase 2 were made through the "Atout Age" workshops, it was necessary to understand the relationship to these workshops to ensure the best possible participation and adherence. Acceptance of the prevention workshops and screening tools was an essential condition for implementing a frailty screening pathway.

2.1.2. Phase 1: methods

Based on a theoretical framework constituted at the frontier of the sociology of uses, innovation, ageing and interactionist sociology in health, a qualitative survey was conducted in 2016 and 2017. It was based on 44 semi-directive interviews with Reunion Islanders aged between 55 and 87 years old and through numerous participating and non-participating observations [24]. Observations were made during prevention workshops and during the first measures of phase 2.

The objectives of this survey were:

1. To better understand and conceptualize the acceptability process,
2. To identify the possible obstacles and facilitators of prevention and new health technologies,
3. To collect the perception of respondents regarding their participation in prevention workshops,
4. To accompany the deployment of the following phases of the project. The interview grid was built around several themes: the life course, the relationship to innovation, the relationship to prevention and the relationship to technology.

The "Atout Age" workshops are prevention workshops on the themes of mobility, nutrition and housing. The workshops have been built with the collaboration of a committee of experts: doctors from the *Centre hospitalier universitaire* (CHU) of *Reunion*, the *Institut de recherche pour le développement (IRD)*, the *Centre national de la recherche scientifique (CNRS)*, the *Caisse générale de sécurité sociale* (CGSS), the *centre communal d'action sociale* and the associative network of Reunion Island. The aim of the workshops is to reinforce the quality of life and health-protective behaviors such as the recommendations "eat 5 fruits and vegetables a day, practice regular physical activity" from the French public health institute, among retired people over 55 years old. Practical and simple advice to be carried out in daily life is given. Also, the strengthening of social ties by meeting new people sharing the same interests is sought. During the 5P program, we focused on the "Atout Age mobility" workshops. These are physical exercise sessions of 60 min per week for a period of 12 weeks. It is a combination of walking, balance, coordination and muscle strengthening exercises [25].

2.1.3. Phase 1: results and discussion

This qualitative survey showed that the people surveyed were extremely satisfied with the prevention workshops they attended. A collective "blues" was even identified at the end of the sessions and the protocol [26]. This satisfaction is largely linked to the group dynamics created in the workshops and also to the learning of good practices.

Concerning health and autonomy technologies, it was possible to better understand the process of acceptability and to propose a new definition. "A movement, in permanent reconfiguration, in which elements, which carry subjective values more or less objectified by individuals, interact, add up and produce a meaning. This definition thus makes it possible to differentiate between acceptability (process) and use (state with greater or lesser intensity at a time t)" [27]. On the basis of this definition, we analyzed the situations of use and non-use and concluded in our study that health and autonomy technologies are accepted insofar as they have significant use value for individuals, meet individual needs and are carried and proposed by authority figures such as health professionals [26–29].

2.2. Phase 2: 5P-PILOT study

2.2.1. Phase 2: introduction

The 5P program is an interdisciplinary research program targeting the primary prevention of loss of autonomy among seniors through adapted physical activity workshops. Setting up a large-scale clinical trial of the effectiveness of primary prevention interventions on frailty requires testing research procedures and the feasibility of such a study. The objective of the 5P PILOT study was to determine this feasibility.

2.2.2. Phase 2: methods

The pilot study was carried out from September 04, 2017 to January 29, 2019 at the University hospital center (CHU) of Reunion Island with 3 months of follow up between two visits. Were included retired people aged ≥55 years among participants in the "Atout Age Mobility" workshops, in the cities of Saint-Pierre and Saint-Joseph, Reunion, France. Were excluded participants with a contraindication to sport, iso resource group score lower than 5 [30], under safeguard procedure (curatorship, guardianship) or legal proceedings and people who does not understand French. It was evaluated: adherence to the protocol, recruitment, eligibility criteria, the "Smart Check®" prototype to help assess frailty.

The "Smart Check®" tool, developed by the Borrelli laboratory, financed by the technology transfer acceleration company (SATT)-IDF Innov, which became Erganeo in June 2019, is an example of a screening tool. It consists of a touch-sensitive tablet combined with accelerometers (Xsens®) and a force platform (Wii balance board from Nintendo®) that can respectively record walking and balance movements. A computer server produces the mathematic analyses in real time (Fig. 1). The "Smart Check®" system is now marketed by Engie® under the name AbilyCare®. Walking and balance are two indicators of a person's state of robustness. This tool allows objective tests of gait and balance to be carried out by health professionals. It is part of the identification and long-term monitoring of the robustness status of seniors [20].

Fig. 1. « Smart Check® » system.

2.2.3. Phase 2: results and discussion

Ninety-six patients were included. The mean age of the population was 68 ± 8 years. The vast majority of subjects were female (n = 83, 91.2%). According to Fried et al. 52 (58.4%) were robust, 34 (38.2%) pre-frail and 3 (3.4%) frail. Adherence to the protocol was mostly respected: The consent collection rate was 100%. The erroneous inclusion/exclusion rate was 8.3%, 5 people were erroneously included, 2 on age criteria and 3 on GIR <5, 3 others were erroneously excluded because they had previously completed the workshops. The data completeness rate was greater than 98% for all tests for the initial visit. For the final visit, the completion rate for the physical tests remained > 98%. The mean difference between the initial visit and the final visit was approximately 5 months ± 2 months.

The inclusion rate made it possible to include the 1000 patients required for scaling up. The protocol was modified to include more frail and male ambulatory patients due to selection bias.

The mean time to complete the balance measures was 20 min. On average, a technical acquisition problem, requiring the repetition of the measurement, occurred every 4 measurements for the locogram and every 10 measurements for the statokinesiogram. Non-comprehension of the instructions by the patients was at the origin of one measurement error out of 20. The "Smart Check®" prototype was considered acceptable subject to a decrease in the frequency of tool acquisition problems.

Phase 2: conclusion. A large-scale clinical trial to evaluate the effect of the "Atout Age Mobility" workshops on seniors' mobility and quality of life and to improve the "Smart Check®" diagnostic tool is feasible, subject to improvements in protocol procedures [25].

2.3. PHASE 3: 5P-SCALE clinical trial

2.3.1. Objectives

The main objective is to measure with sufficient power the impact of prevention workshops on the physical performance and quality of life of seniors. Secondary objective is to improved detection of frailty and pre-frailty by using quantitative and longitudinal approaches [31].

2.3.2. Study sample

This phase 3 of the 5P program will be conducted in 10 offices of general practitioners in Réunion. All subjects screen for participation will be 65 years or older and among patients of general practitioners or participants in "Atout Age Mobility" prevention workshops.

Eligible patients will be retired persons aged ≥65 years, person retired from the general scheme, person affiliated, or beneficiary of a social security scheme and free and informed consent given. Will be excluded participants with a contraindication to sport, under safeguard procedure (curatorship, guardianship) or legal proceedings and people who does not understand French.

2.3.3. Study design

This study is a pseudo-randomized, controlled, ambulatory, single-blind, parallel clinical trial. A **pre-inclusion visit** will be dedicated to informing the patient about the research program and to check whether the patient meets the participation criteria. It will be carried out either by the patient's attending GP or an adapted physical activity (APA) monitor who conducts the "Atout Age Mobility" workshops.

The patient will then be referred to the Investigating General Practitioner (IGP) for **the inclusion visit**: if the patient agrees, the IGP will check the eligibility criteria and then obtain the patient's written consent after informing them.

Then, the IGP will contact the project manager who will assigned **pseudo-randomly** patient to study groups to the intervention or con-

trol group according to the limited local recruitment capacity of the prevention workshops and patients not included in the intervention group due to lack of available places will be included in the control group. In order to limit imbalances, the recruitment of control patients will be limited to 2 per 1 patient included in the intervention group. Each IGP, blinded to study groups, will enroll 5 to 10 patients per month for a 6-month follow-up.

Control group. Patients will receive standard care according to current medical recommendations.

Intervention group. Patients will follow the "Atout Age Mobility" workshops within 6 months. These are physical exercise sessions of 60 min per week for a period of 12 weeks. It is a combination of walking, balance, coordination and muscle strengthening exercises [25].

After the inclusion, **the initial visit** can be carried out directly after the inclusion or within 15 days by the IGP. This will be completed by a telephone survey. **A final visit** will be conducted 6 months after inclusion. It is the same for all participants. Fig. 2 illustrates the overall design of "the scaling-up" with the pre-inclusion phase, inclusion, pseudo-randomization and follow-up visit.

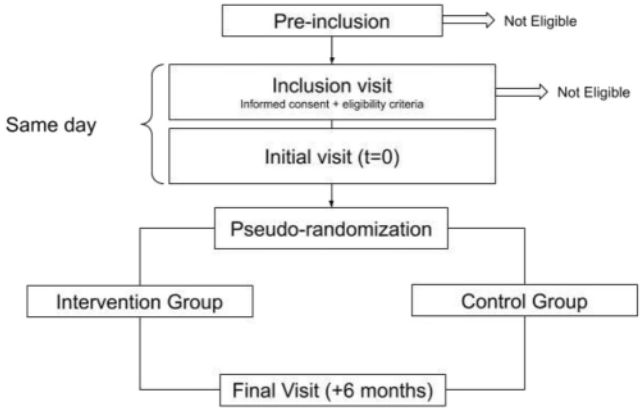

Fig. 2. Design of phase 3 scaling UP of the 5P program.

2.3.4. Measurement and outcomes

Outcomes measures included at the initial visit:

- Collection of socio-demographic data
- Assessing Health Precariousness and Inequalities: EPICE Questionnaire [32].
- Quality of life and anxiety questionnaires: Short-Form-36 (SF-36) [33], HADS Hospital anxiety and depression scale (HADS) [34], SAPAS De Moran [35].
- Assessment of frailty via "Smart Check®" [20]: CES-D Depression Scale [36], Grip strength test [37], gait speed, weight and height, the Short physical performance battery (SPPB) [38].
- *"Enquête sur la santé et la protection sociale"* questionnaire (ESPS) 2012 [39].
- CGSS workshop questionnaire 2019 version
- Mobility and balance measures "Smart Check®" [25].

The primary intervention efficacy tests are defined on the SF36 for quality of life, gait speed and SPPB for physical performance. Secondary outcomes are mobility and balance instrumental measures "Smart Check®" [25] and frailty assessment. Primary, secondary outcomes and telephone survey will be repeated for the final visit. Data from CGSS workshop questionnaire will be collected from participants' records. In order to verify the correct participation of patients in the intervention, follow-up data from the workshops will be used. The IGP will not have access to the data obtained at the first visit in order to limit interpretation bias. Table 2 shows the planning of the follow-up visits and their contents.

2.3.5. Sample size

From a mathematical point of view, estimating the correct sample requires a prior knowledge of the solution (i.e. the true distribution of the underlying model) to answer correctly, which goes against the purpose of the question. However, it is possible to answer a slightly differ-

Table 2
Summary of participatory monitoring of phase 3 of the 5P Program.

	Pre inclusion	Inclusion	Initial visit	Experimental group	Control group	Final visit
Chronology (months)	- 0,5	0				+6
Pre-inclusion questionnaire	x					
Patient information	x					
Informed consent		x				
Checking the inclusion/exclusion criteria		x				
Pseudo randomization		x				
Questionnaires[a]		x				
- EPICE						
- HADS						
- SAPAS de Moran						
Assessment of key judgement criteria:			x			x
- SF36						
- SPPB						
Frailty Assesment[b]			x			x
Instrumental measures[c]			x			x
- Statokinesigram						
- Locogram						
Telephone surveys:			x			x
- ESPS						
- CGSS						
"Atout Age Mobility" workshop				x		
Evaluation of workshop follow-up[d]		x	x	x	x	x
Adverse reaction research		x	x	x	x	x

[a] Questionnaires for the initial assessment carried out at the end of the inclusion visit, HADS will also be carried out during the final visit.
[b] Fragility assessment: CES-D Depression Scale, Grip test, weight and height measurement.
[c] "Smart Check®" instrumental measurements: balance measurement on force platform and walking measurement with sensors over 10 m.
[d] CGSS presence indicators at the workshops.

ent question: "How many data points are needed to conclude if two populations are different by at least $c > 0$ with a confidence of at least 95%?". In this case, we can answer this question using for example a non-parametric approach based on concentration inequalities (see for e.g Bercu et al.12). In our case, one of the consequences of the Azuma Hoeffding inequality is that a sample size of 1000 people, with at least 300 frails patients, would make it possible, for example, to answer if there is a difference of at least 0.25 between the average SPPB of frail and non-fragile individuals. From a clinical point of view, the calculation of the number of subjects needed requires less inclusion than the data needs for the improvement of algorithms for the detection of frailty at early stages.

2.3.6. Statistical analysis

All data will be collected via an e-Case Report Form. Distributions of Gaussian variables will be represented by mean and standard deviation (SD) (mean ± SD). Categorical variables will be expressed as counts and percent frequencies. Statistical methods will be performed to compare means using the Wilcoxon signed rank test and proportions with the Chi-square test. A Bonferroni statistical correction will be applied if necessary. For secondary objective, the omnipresence of sensors during the measurements (force platform and gait sensors) will generate massive flows of multidimensional and heterogeneous data. We do not forbid any type of statistical modelling, whether conventional or innovative. The work will be carried out in two stages: The first step will consist in the discovery of these statistical descriptors. The second stage will focus on decision-making aspects (classification, recommendation of actions, detection of anomalies and risk indicators). This stage will rely on advanced mathematical tools for signal analysis, classification and statistical predictive modelling. The aim of mathematical modelling is to identify key quantities for the quantification of behavior and monitoring of seniors. Data analysis and statistical processing will be carried out at two different levels: within individual measurements (individual longitudinal follow-up) and across measures of the whole patient population (population follow-up). Main tools will be: multivaried homogeneity tests for high comparison of sample sizes, learning algorithms for anomaly detection (one-class SVM, etc.), and tests for optimizing detection performance in terms of ROC curves and longitudinal data analysis.

2.3.7. Ethics and regulatory

This study was approved by the Research Ethics Committee of the University of Paris (No. IRB 2020–05). The data collection and the protection measures will be validated by the National Commission for Information Technology and Civil Liberties (CNIL). The protocol will be registered on clinicaltrial.gov.

3. Discussion

Currently, few trials are being conducted in primary care to evaluate frailty identification tools and measure the effectiveness of primary prevention interventions on loss of autonomy.

The results of the 5P program will provide evidence to the economic interest group "active aging" and the regional health agency for the implementation of a personalized care pathway for the prevention of loss of autonomy in Reunion Island. This evidence is necessary in order to comply with the quality criteria for a screening program which have been summarized in the methodological guide of the national health accreditation and evaluation agency [40].

Frailty is an early stage of loss of autonomy. Its epidemiology is well known and its medico-economic impact has been established [3]. The gold standard for the diagnosis of frailty remains the criteria of Fried et al., which were derived from a 7-year follow-up of a population of 5317 people [37]. The reference intervention in the prevention of loss of autonomy remains the comprehensive geriatric assessment. It has proven its effectiveness in reducing morbidity and mortality [16]. However, these are time-consuming procedure that cannot be used in general practice.

With the 5P program, we want to transfer a simplified, objective version of the CGA and frailty to primary care. We expect that the diagnostic tests will improve the selection of the subjects most in need of a CGA.

The tests evaluated in the scale-up phase should allow the identification of frailty in a simple and reproducible manner. Other tests for identification and management have also been evaluated in the research program "The MIND project" [22]. These studies are essential for building solid references for the prevention of loss of autonomy.

The data from this program will provide information on the real impact of the "Atout Age" prevention workshops. They will support the promotion of prevention activities based on scientific evidence.

At present, clinical trials in general medicine are still infrequent, particularly in La Réunion where the majority of clinical trials are hospital-based. The GRAMOUNE CARE epidemiological study has brought a great deal of experience to general medicine researchers of Reunion with the creation of an investigation network. The 5P program will bring additional experience in the execution of large ambulatory clinical trials. We expect to encounter organizational constraints that may lead to methodological biases. The program's experience will enable the methodological and organizational improvement of clinical trial protocols in general medicine while complying with the quality criteria of the international council on harmonization for clinical trials. Due to COVID-19 Pandemic, the implementation of this clinical trial is suspended until the "Atout Age Mobility" workshops are re-established. The added value of the 5P program lies in its interdisciplinary approach. Also, the contribution of objective measurement tools based in particular on neurophysiology, sociology, mathematics and the medical clinic will allow more precise measurements of frailty that can be used by the greatest number of people.

The data resulting from this project will make it possible to provide many elements of answers for the implementation of a targeted screening program for frailty.

Link of interest

The authors do not declare any link of interest.

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Author declaration

1) We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.
2) We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.
3) We confirm that neither the entire paper nor any of its content has been submitted, published, or accepted by another journal. The paper will not be submitted elsewhere if accepted for publication in the Journal.

4) We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.
5) We confirm that any aspect of the work covered in this manuscript that has involved either experimental animals or human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.
6) We understand that the Corresponding Author is the sole contact for the Editorial process (including Editorial Manager and direct communications with the office). He/she is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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