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Implementation of a strategy involving a multidisciplinary mobile unit team to prevent hospital admission in nursing home residents: protocol of a quasi-experimental study (MMU-1 Study)

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1 **Implementation of a strategy involving a multidisciplinary mobile unit team to prevent hospital**
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3 **admission in nursing home residents: protocol of a quasi-experimental study (MMU-1 Study)**
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60

ABSTRACT

Introduction- Nursing home residents represent a particularly vulnerable population experiencing high risk of unplanned hospital admissions, but few interventions have proved effective in reducing this risk. The aim of this research will be to verify the effects of a hospital-based multidisciplinary mobile unit (MMU) team intervention delivering urgent care to nursing home residents directly at their bedside.

Methods and analysis- Four nursing homes based in the Parma province, in Northern Italy, will be involved in this prospective, pragmatic, multicenter, 18-month quasi-experimental study (sequential design with two cohorts). The residents of two nursing homes will receive the MMU team care intervention. In case of urgent care needs, the nursing home physician will contact the hospital physician responsible for the MMU team by phone. The case will be triaged as a) manageable by phone advice, b) requiring urgent assessment by the MMU team or c) requiring immediate ED referral. MMU team is composed of one senior physician and one Emergency-Medicine resident chosen within the staff of Internal Medicine and Critical Subacute Care Unit of Parma University-Hospital, usually with different specialty background, and equipped with portable ultrasound, set of drugs and devices useful in urgency. The MMU visits patients in nursing homes, with the mission of stabilizing clinical conditions and avoiding hospital admission. The residents of the other two nursing homes will receive usual care, i.e. ED referral in every case of urgency. Study endpoints include unplanned hospital admissions (primary), crude all-cause mortality, hospital mortality, length of stay and healthcare-related costs (secondary).

Ethics and dissemination- The study protocol was approved by the Ethics Committee of Area Vasta Emilia Nord. Informed consent will be collected from patients or their legal representatives. The results will be actively disseminated through peer-reviewed journals and conference presentations, in compliance with the Italian law.

Registration ID- ClinicalTrials.gov NCT 04085679

Key words: multimorbidity; geriatrics; hospitalization; multidisciplinary care; hospital-community partnership

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ✓ This study will explore the effectiveness of a complex intervention focused on the avoidance of hospital admissions for nursing home residents, with a strong hospital-community partnership.
- ✓ The study intervention consists in bringing specialist hospital care directly at the bedside of nursing home residents, an innovative approach not previously described in the scientific literature.
- ✓ The intervention has been developed considering the organization of Italian healthcare system, but is reproducible and applicable in other settings.
- ✓ Due to ethical concerns and complex nature of the intervention, randomization of participants is not possible.

For peer review only

INTRODUCTION

The increasing clinical complexity of older medical patients in industrialized countries, due to multimorbidity, polypharmacy, frailty, disability and social hardship, is challenging for health care systems.^{1 2} Firstly, these patients are often admitted to Emergency Departments (EDs), accounting for 12 to 24% of all ED visits.³ However, their complex needs are often poorly met in this setting, where the busy, overcrowded environment does not always allow a careful evaluation of the multi-faceted clinical problems of elderly patients.⁴⁻⁶ These difficulties not only contribute to ED overcrowding, but they may also lead to inaccurate diagnoses and unrecognized or untreated health problems.⁷ Older patients furthermore have an up to 5-times-higher risk of ward admission, irrespective of the severity of the clinical problem.^{3 5 8} Once admitted, they are far more likely to stay in hospital for more than two weeks⁶ and are at much greater risk of experiencing complications related to hospital admission.⁹

These issues are especially relevant for residents of nursing homes, who exhibit a particularly high risk of hospitalization (greater than 20% per year)¹⁰ and are at high risk of complications during hospitalization, due to frailty, multimorbidity and the possible presence of cognitive impairment.

In the light of these considerations, a number of approaches have been developed designed to reduce the risk of hospitalization in nursing home residents. These are summarized in the very recent systematic review by Santosaputri et al,¹¹ which includes quantitative comparative studies of all designs aiming to determine the efficacy of interventions provided by a health professional specializing in geriatric medicine. Sixteen studies were eligible, of which 6 randomized controlled trials, involving an estimated total of over 7400 patients. The authors of the review categorized 14 intervention programs into three primary approaches (two did not fit in any category):

- Prevention approach (nine studies): Interventions applied in the nursing home to prevent hospitalization of residents, in most cases involving care provided by nurses, physicians, and sometimes allied health personnel. The majority of interventions involved either direct review of patients, telephone (or telemedicine) support, or comprehensive geriatric assessment.
- Emergency department-based hospital avoidance (three studies): interventions targeting nursing home residents presenting to the ED to facilitate early discharge and avoid hospitalization. Programs of this type involved care provided by nursing staff (e.g. intravenous therapy, wound care, catheter management).

- 1 - Post-hospital supported discharge (two studies): Interventions designed to support residents following
2 hospital admission. One of the studies evaluated the efficacy of geriatrician and nurse review in the
3 facility and the development of a comprehensive tailored care plan following hospital admission; the
4 other assessed the efficacy of a tailor-made intervention compared to a standardized rehabilitation
5 program following admission due to hip fracture.
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10 Although the majority of the studies reported reductions in hospitalizations (in the form of either ED
11 presentations or hospital admissions), only six obtained statistically significant findings, of which none were
12 RCTs. Unfortunately, the quality of evidence was considered low to moderate, therefore the authors emphasize
13 the need for further, well-designed studies to identify which interventions are effective in reducing
14 hospitalization in the older residents.
15

16 At our institution, different projects have been carried out for many years to improve care of the elderly,
17 primarily targeting hospital organization, with the main objective to reduce unnecessary, avoidable length of
18 stay (LOS).¹²⁻¹⁴ These efforts benefit in-hospital patients, but are not designed to prevent hospitalizations.
19 Based on literature evidence, and drawing on our long-time experience with elderly care, we hypothesize that
20 a complex intervention delivered in nursing homes, where vulnerable high-risk patients live, involving direct
21 patient care by hospital medical staff with geriatric expertise, may reduce hospitalization of residents.
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39 **METHODS AND ANALYSIS**

40 **Study setting**

41 The study is based in the University Hospital of Parma, which has a catchment area of more than 400,000
42 inhabitants, of whom 22.3% is over 65 years old. It provides the only Emergency service of the district, and it
43 ranks fourth in Italy by number of ED visits (yearly average of over 110,000). The average admission rate of
44 the adult ED population is 18%, of which 65% concern people older than 65.
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50 In the last two decades, the University Hospital of Parma has implemented several innovative initiatives to
51 manage the hospital flow of frail multimorbid patients and their complex needs. These initiatives included bed
52 management to avoid “bed-blockers”,¹² physician accountability for the discharge process,¹³ and creation of a
53 dedicated hospital unit, organized by intensity of care to anticipate the needs of these patients preserving high
54 performance indices.¹⁴ This unit, called Internal Medicine and Critical Subacute Care Unit, performs over
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1 3,500 urgent admissions of frail multimorbid elderly patients per year, with an average length of stay that in
2
3 30% of cases is lower than 3 days.¹⁴
4

5 Nursing homes participating to the study are public facilities which ensure the presence of nursing staff 24
6
7 hours a day and of a physician at least 4 hours a day (high-intensity care facilities). The possible role of distance
8
9 to the hospital is considered by including in each group one nursing home located next to the hospital and one
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11 located >5 km of distance.
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14 The participating nursing homes are the following:
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- 16 - C.R.A. “I Tigli” C/O Comprensorio di Villa Parma, Piazzale Fiume 5, Parma (intervention group)
- 17
- 18 - C.R.A. “Casa degli Anziani”, Via Aldo Moro 2, Collecchio (intervention group)
- 19
- 20 - C.R.A. “Le Tamerici” C/O Comprensorio di Villa Parma, Piazzale Fiume 5, Parma (control group)
- 21
- 22 - C.R.A. “Ines Ubaldi”, Via Ravenna 4, Parma (control group)
- 23

24 This study follows a multimethod approach, based on the MRC framework for developing and evaluating
25
26 complex interventions,¹⁵ including the development, feasibility assessment, and evaluation phases.
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30 **Development of the intervention**

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32 First, the different types of approaches reported in the literature, described above, were considered. The
33
34 “prevention approach”, interventions conducted in nursing homes, was chosen as the most suitable strategy to
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36 integrate the hospital’s organizational model already in place, as it can target both hospitalization rates and ED
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38 overcrowding, allowing to intervene before the person accesses the hospital.
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40 Available evidence also prompted us to opt for a multicomponent approach. In fact, data from qualitative
41
42 interviews reveal that the decision to transfer residents to hospital may be influenced by different factors, such
43
44 as staffing and skill mix in the nursing homes, treatment options available in the facility, end-of-life
45
46 decision-making, and communication and bureaucratic requirements. This multifactorial association means
47
48 that a multicomponent intervention is likely to be more effective than a single-component intervention.¹⁶
49

50 The choice of employing a mobile geriatric specialist service was supported by the positive results obtained
51
52 by the two controlled studies which examined similar interventions.^{17 18} Schippinger et al evaluated a service
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54 where a physician did regular and on-call visits intended to provide services otherwise associated with
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56 hospitalization.¹⁷ Díaz-Gegúndez et al evaluated an ambulant team with a nurse and a physician, doing
57
58 comprehensive geriatric assessments of residents as well as reviewing medications and providing support to
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1 staff.¹⁸ Our intervention does not involve a nurse, unlike the Díaz-Gegúndez study, because in the participating
2 facilities nursing staff is available 24 hours a day. Unlike the experience of Schippinger et al, moreover, we
3 chose not to perform periodic visits on site, since routine clinical management and scheduled follow-up is
4 already performed by nursing home physicians.
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10 Finally, medical hospital staff was preferred to community geriatricians, on the assumption that older patients
11 may feel more comfortable being handled by physicians who may have already cared for them at the hospital.
12 Moreover, hospital staff enables direct patient referral to the ward. Finally, this allows the use of diagnostic
13 technologies available at the hospital, which can be used immediately without the need for hospital admission.
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20 **Description of the intervention**

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22 The model hinges on the strong collaboration between hospital and nursing home staff to provide residents
23 with patient-centered care. It entails a multicomponent intervention which is integrated in standard care and
24 comprises three steps: 1) MMU team activation, 2) on site visit by a team of physicians with geriatric expertise,
25 3) interdisciplinary care planning (Figure 1).
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33 *Step 1: MMU team activation*

34 Patient selection is necessary to ensure that available resources are used for patients who may really benefit.
35 To this end, the nursing home physician contacts by phone the “flow manager”, a skilled internist with strong
36 clinical expertise, organizational attitude and managerial training, during the 8 a.m.-6 p.m. time frame, Monday
37 to Friday. The phone consultation is reported on a form containing the description of the patient’s clinical
38 condition and a summary of the conversation. The form also indicates which decision was reached among the
39 following 6 not mutually exclusive options:
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- 47 a) The patient can be managed by nursing home staff, therapeutic advice is provided by phone
- 48 b) Remote reassessment is scheduled after a number of hours agreed upon by the team
- 49 c) The MMU team is dispatched for evaluation, treatment and stabilization on site
- 50 d) A significant change in vital parameters is observed which requires immediate activation of emergency
51 services
- 52 e) Direct hospital admission is considered necessary
- 53 f) Ambulatory outpatient visits or tests are planned
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4 *Step 2: on site visit by a team of physicians with geriatric expertise*

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6 Visits at the nursing home are performed by two members of the MMU team: an expert hospital physician
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8 chosen on a case-by-case basis among the clinical staff of the Internal Medicine and Critical Subacute Care
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10 Unit, which comprises internists, gastroenterologists, geriatricians, specialists in clinical nutrition, depending
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12 on the disease or clinical problem that must be treated, and a specifically trained resident in Emergency
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14 Medicine.

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16 The team is provided with a car to reach the nursing homes, a portable ultrasound system, and an essential set
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18 of drugs and medical devices useful in an emergency setting. The ultrasound system is equipped with three
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20 probes (convex, linear, and phased-array) for performing thoraco-pulmonary, cardiac, vascular, abdominal and
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22 soft tissue ultrasound, when required. Available drugs include those that can be administered intravenously for
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24 treating urgent conditions (e.g. loop diuretics, steroids, fluids, antibiotics). Devices include central and
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26 peripheral venous lines, naso-gastric and rectal tubes and bladder catheters. Blood tests can also be performed.
27
28 Table 1 shows possible clinical scenarios which may require MMU team activation, and possible decisions.

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33 *Step 3: interdisciplinary care planning*

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35 Based on the results of the visit and of any performed investigations, the MMU team formulates personalized
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37 advice and referrals, and discusses these with the nursing home physician. If stabilization on site is not deemed
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39 possible, the MMU team plans a direct admission to the Internal Medicine and Critical Subacute Care Unit,
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41 thus avoiding ED access. The planning and the final outcome of the intervention are recorded in the second
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43 part of the form.

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47 **Feasibility assessment**

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49 A pilot phase of 5 months (December 2018-April 2019) was conducted in two nursing homes in order to look
50
51 at feasibility of the MMU care Model described above. Before the intervention was introduced, meetings were
52
53 held with nursing home staff to agree on activation modalities.

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55 In this period, 99 phone calls were received, of which 84 required MMU team onsite visits, and 15 were
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57 managed with remote consultancy. Of the latter, 3 required direct admission after remote phone consultancy.
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1 Only 4 of the 84 patients visited onsite required direct admission. One patient was sent to the ED for massive
2 intestinal bleeding (Figure 2).
3

4 This phase demonstrated the feasibility of the intervention, and did not highlight any need for modifications.
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9 **Evaluation phase**

10 *Aim and objectives*

11 The study aim is to verify the effects of the implementation of the MMU care model tested in the pilot phase.
12
13 Primary objective is to verify reduction of unplanned hospitalization rates in the nursing homes of the
14 intervention group compared to the nursing homes in the control group. Secondary objectives are to measure
15 the effects of the intervention in terms of mortality, health service use, and costs.
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23 *Study Design*

24 This study is a prospective, pragmatic, multicenter, quasi-experimental study (sequential design with two
25 cohorts), in which usual nursing home care is compared to care provided by applying the MMU model.
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33 *Study Population*

34 All residents of the participating nursing homes are eligible, regardless of their clinical status. Residents who
35 do not provide informed consent will be excluded.
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41 *Usual Care*

42 Patients in the control cohort receive usual care, which means the actions to take are decided by the nursing
43 home staff. Generally, this implies that patients who are clinically unstable, or require urgent instrumental
44 tests, will be sent to the ED.
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51 *Measures: Baseline variables*

52 Demographic data on gender and age are collected by chart review.
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58 *Measures: Outcome variables*

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1 The primary outcome is hospitalization rate, considering at the numerator all unplanned admissions occurred
2 during a 1-year period, and at the denominator the sum of the person-time of the at risk population (days of
3 stay at the nursing home). For the intervention group, the numerator corresponds to options d) and e) defined
4 in “Step 1: MMU team activation”.

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9 The secondary outcomes are the following:

- 10 - Crude all-cause Death Rate (CDR): the number of deaths *during a* 1-year period on person-time of the
11 at risk population
- 12 - Hospital Mortality rate: the frequency of patients who die while in the hospital (death rate/1000)
- 13 - Length of stay (LOS): the duration of a single episode of hospitalization. Inpatient days are calculated
14 by subtracting day of admission from day of discharge.
- 15 - Adverse events or complications: frequency of events occurred within 48 hours from MMU team
16 activation and subsequent patient stabilization, for which hospital access becomes necessary.
- 17 - Costs analysis, comparing the cost differences in the two groups

30 31 *Data Collection*

32 Patient demographic and clinical characteristics are collected at baseline to describe the study population and
33 determine factors associated with hospital rate. Participants’ files and electronic data are stored securely at the
34 study site (e.g. locked area, password protected hard- and software). Data integrity will be scrutinized with
35 several strategies (e.g. valid values, range checks, consistency checks). Patient data are only identifiable with
36 the unique participant’s number. Personal information will be collected and saved in a separate file (on a
37 different server) which can only be accessed by the Principal Investigator (PI). This information will be used
38 by the PI to retrieve data on any hospital admissions (length of stay, in-hospital death ...) from administrative
39 databases (discharge summaries, ED data, Death Registry). Residents’ identification data will be deleted once
40 the study is completed, making the dataset anonymous. All study protocol authors will have access to the
41 anonymous dataset.

52 53 54 55 56 *Cost analysis*

57 We will identify the changes in net costs associated with one-year exposure to the intervention, consisting in
58 the induced costs due to incremental resource inputs for carrying out the intervention and hospital health
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1 service utilization costs. Staffing costs will be calculated considering the time spent by the professionals
2 involved in the intervention. Non-staff running costs include expenses of MMU staff travelling to and from
3 the nursing home. The health service utilization costs will be identified based on the Diagnosis Related Group
4 (DRG) system.
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10 11 *Study duration*

12 Overall expected duration is 18 months, with study initiation presumably in November 2019 and completion
13 in April 2021.
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18 19 **Statistical Methodology**

20 21 *Sample size calculation*

22 The number of subjects to include was estimated using the findings of Diaz-Gegundez et al [Diaz 2011], who
23 performed a large quasi-experimental trial. Thus, considering 56 cases vs 32 cases per 100 residents, and using
24 a 2-sided, large-samples z-test of the Poisson incidence rate difference at a significance level of 0.05, and with
25 a power of 0.90, overall 338 residents should be enrolled.
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33 34 *Statistical analysis plan*

35 Descriptive statistics will be used to summarize patient populations and will be presented as means and
36 standard deviations (SD) when normally distributed, or as medians and interquartile ranges (IQR).
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39 For the primary analysis we will use Poisson regression with robust standard errors (SEs) to evaluate relative
40 differences in hospital rates among our two cohorts while adjusting for demographic characteristics.
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43 Concerning the secondary outcomes, the following analyses will be performed:
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- 46 - Rates will be compared considering the quotient between the intervention and control groups
- 47 - A lognormal model will be used to compare in-hospital LOS.
- 48 - Chi square tests will be conducted for categorical data as adverse events or complications
- 49 - For costs, we will use the following equations to summarize the annual net costs associated with the
50 implementation of the intervention. Any costs with negative values mean “savings” and any costs with
51 positive values mean “losses”. Net costs = A (intervention costs) ± B (Costs for differences in hospital
52 health service utilization) where: A= intervention: staffing costs+intervention: non- staff costs and B=
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1 Costs for differences in inpatient care utilization. Therefore, the net costs arising from one-year
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3 implementation of the intervention as compared with the current practice will be obtained, where a
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5 negative value of net costs represents “cost-saving” and a positive value represents “not cost-saving”
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7 The demographic and clinical variables which influence the outcome with a p value<0.20 in the univariate
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9 analysis will be included in the Poisson regression model.
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11 The analyses will be performed using SAS 8.2 (SAS Institute, Cary, NC, USA) and STATA-SE 11 (Stata Corp
12
13 LP, College Station, TX, USA).
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20 **ETHICS AND DISSEMINATION**

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22 The study will be conducted in compliance with the principles of the revision of the Helsinki Declaration and
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24 by current legislation on scientific research. The protocol and the patient informed consent form have been
25
26 approved by the competent Ethics Committee, in accordance with Italian current norms. The study protocol
27
28 has been registered on ClinicalTrials.gov (NCT 04085679).
29

30 This study does not entail any experimental pharmacological treatment, or changes in the diagnostic-
31
32 therapeutic pathway. Eligible patients will be asked to give consent to handling of their personal data in writing.
33
34 The consent form will be dated and signed by the patient and by the investigator, authorized according to
35
36 norms of the local Ethics Committee.
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39 A copy of the signed informed consent form shall be given to the patient, and the original shall be retained by
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41 the investigator as part of the study documentation. Informed consent is required for all patients, also in the
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43 control group. Informed consents are obtained by nursing home physicians, who are in charge of enrolment. In
44
45 the case of persons incapable of giving informed consent according to the investigator (such as patients with
46
47 dementia), consent will be sought from a legal representative.
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49 If a patient wishes to discontinue his/her participation in the study, it is the responsibility of the investigator to
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51 ensure that no further data regarding the person’s health condition shall be collected. All collected data will be
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53 used in the final analysis.
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55 All data collected, handled and stored for the purpose of this study will be kept confidential at any time and
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57 will be securely stored, as required in GCP guidelines and in current privacy legislation. All data will be
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59 gathered anonymously and handled by the project team in charge of analysis and management.
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1 The Promoter of the study is the University Hospital of Parma, which therefore maintains ownership of data.
2
3 The Research and Innovation Unit of the University Hospital of Parma is responsible for data management
4 and statistical analysis. Findings will be published under the responsibility of the study's promoter. Authorship
5 will be determined in compliance with International Committee of Medical Journal Editors (ICMJE)
6 recommendations.
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Contributors

A.N., B.P., S.L., P.M., E.B., M.F. and T.M. conceptualised the project and designed the intervention. F.D., A.T., P.S., F.P., B.S. and C.C. provided relevant contributions for study conception and design. E.I. gave statistical consult. A.N., C.C., F.D. and A.T. drafted the manuscript. All the authors read and approved the final manuscript.

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Competing interests

None declared.

Patient consent

Not required.

Ethics approval

The study was approved by the competent Ethics Committee (Comitato Etico Area Vasta Emilia Nord), under the ID 846/2019TOSS/AOUPR.

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TABLE 1

Overview of possible expected clinical situations for which a Multidisciplinary Mobile Unit consultation may be activated, and possible management.

Clinical situation	Clinical question	Mobile Unit Intervention	Disposition
Dyspnea of unknown origin	Pulmonary? Cardiac? Embolism? Other causes?	Chest and Abdomen Ultrasound. Arterial Gas sample, ECG, intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Abdominal pain	Gallbladder stones? Cholecystitis? Renal colic? Diverticular disease? Urinary retention? Faecal impaction? Peritonitis? Ascites? Acute/subacute Hernia?	Abdomen ultrasound, basic blood tests, intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Hematuria	UTI? Catheter dysfunction? Bladder polyps? Stones?	Abdomen ultrasound, Bladder lavage, Catheter (re-)positioning, Intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Psychomotor agitation in previously stable dementia	Inadequate therapy? Emerging internistic problem? Other	CGA, Neurogeriatric visit, exclusion of internistic-emerging problem, ECG, Thoracic&abdominal US	Appropriate diagnosis and treatment on site.
Fever	Origin?	Thoracic&abdominal US, basic blood test	Excluding common differential diagnosis
Absence of peripheral veins for drugs or nutrients infusion	How to find adequate venous access	US guided Central venous catheter or PICC or peripheral access	Securing patient
Monolateral leg edema	DVT? Erysipelas? Trauma?	Venous and soft tissues ultrasound	Appropriate diagnosis and treatment on site.
Terminal illness	Palliation strategy? How to get symptoms relief?	CGA. Multidisciplinary assessment. Positioning of drains (eg abdominal drainage for ascites). Interview with relatives / caregivers and GP for sharing strategies	Appropriate management.
Ultrasound exam in a patient who can be transported with difficulty	GP's question	Abdominal, cardiac, arterial, thyroid, neck ultrasound	Appropriate assessment

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2 ECG = Electrocardiogram; UTI = Urinary Tract Infection; CGA = Comprehensive Geriatric Assessment; US = Ultrasound; PICC = Peripherally-Inserted Central Venous
3 Catheter; DVT = Deep Vein Thrombosis; GP = General Practitioner.
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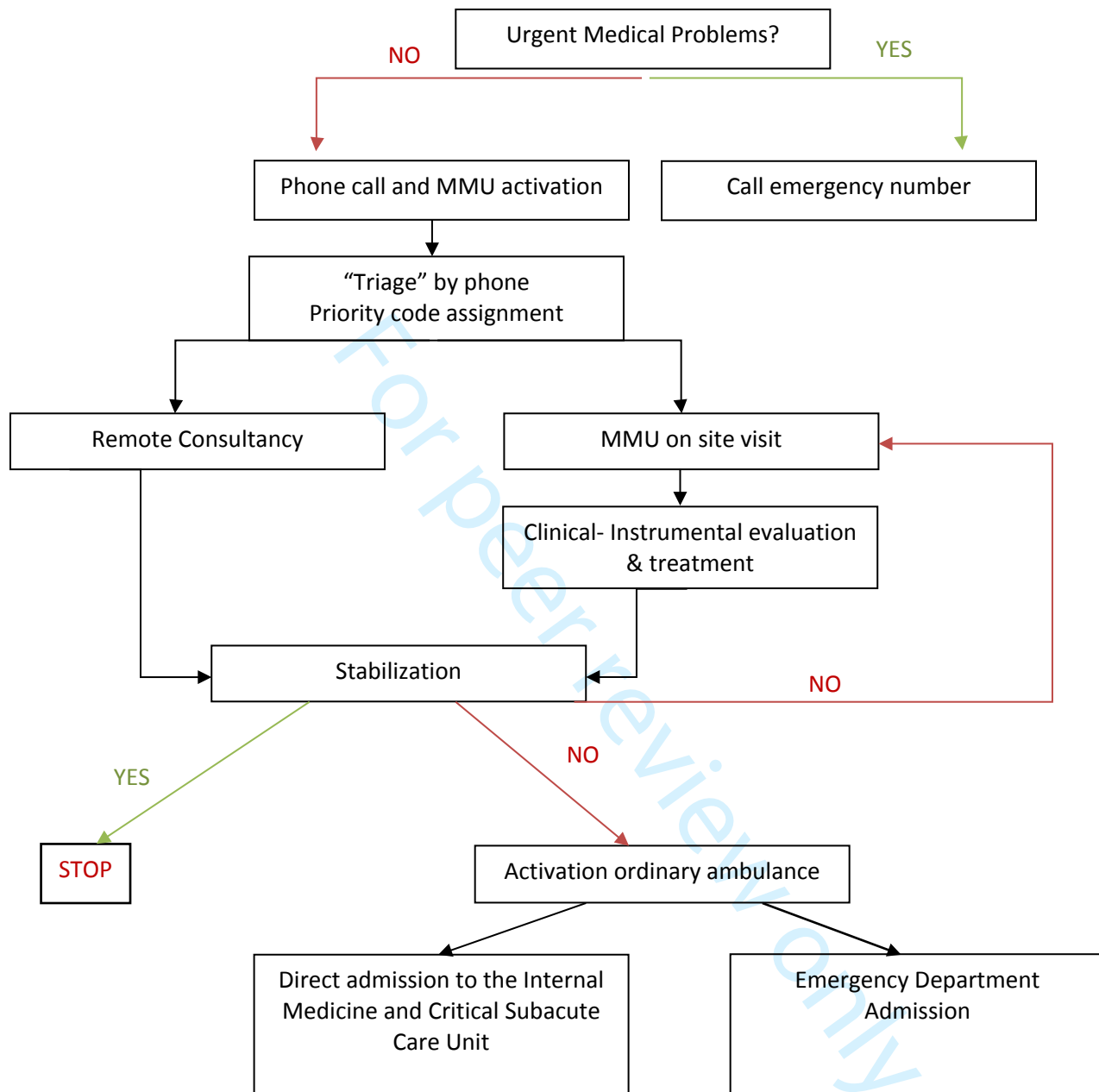
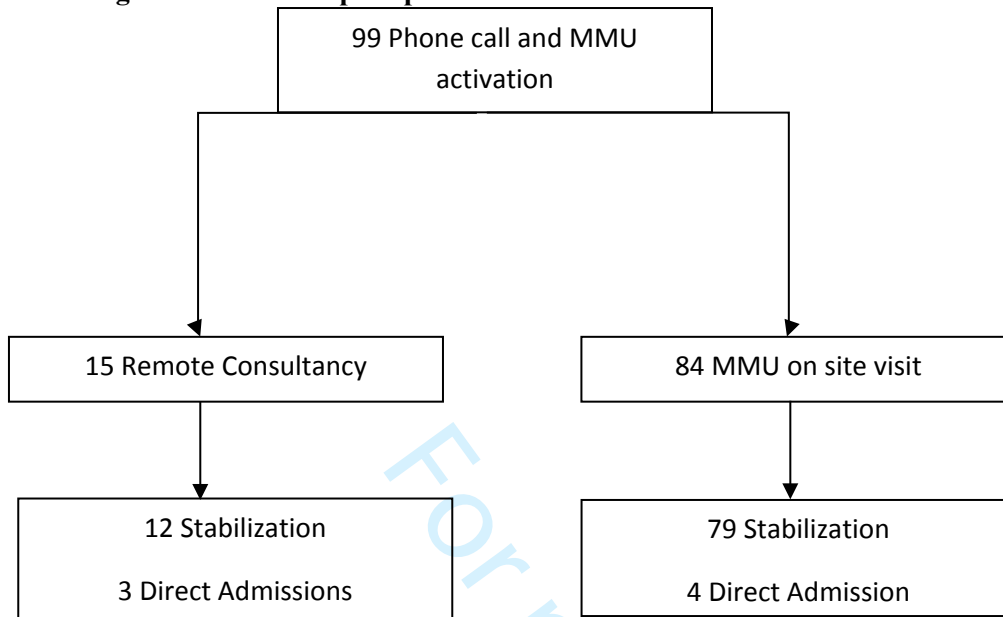


Figure 2. Results of pilot phase

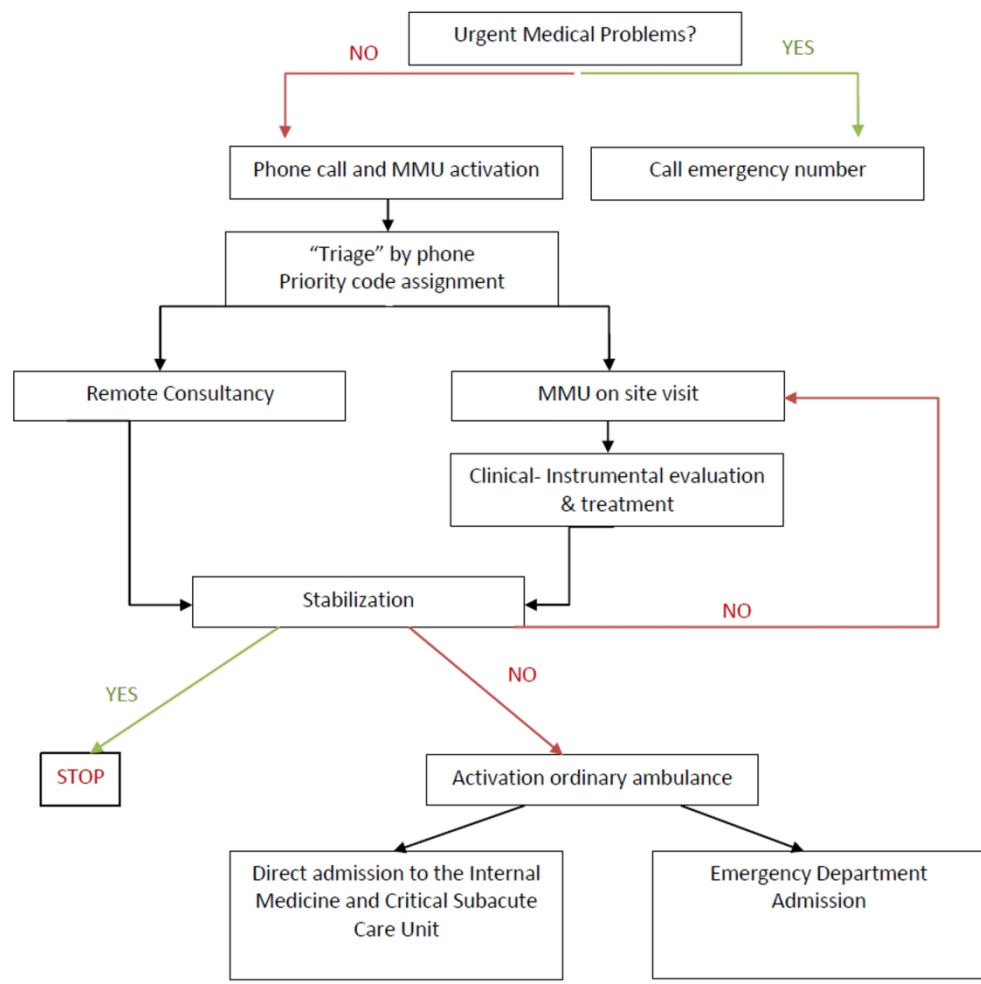
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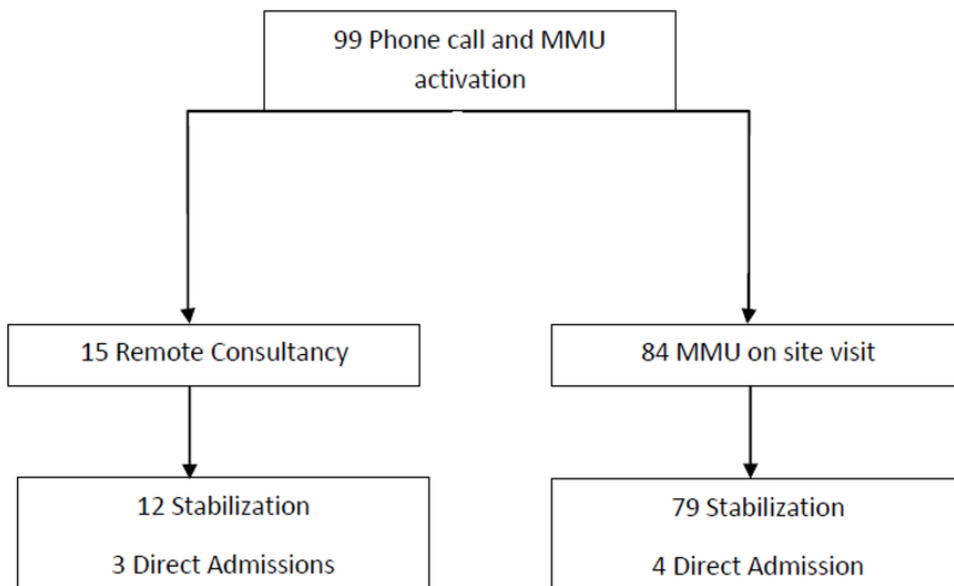
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Description of the intervention of MMU Team

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Results fo the pilot phase

76x44mm (300 x 300 DPI)

MMU-1 STUDY PROTOCOL

Implementation of a strategy to prevent hospital admission in nursing home residents: protocol of a quasi-experimental study

Promoter: Azienda Ospedaliero-Universitaria di Parma

Principal Investigator: Prof. Tiziana Meschi, U.O.C. Medicina Interna e Lungodegenza Critica, Dipartimento Medico-Geriatrico-Riabilitativo, Azienda Ospedaliero-Universitaria di Parma

Protocol ID: MMU-1

Version: n.2 of 2/10/2019

ClinicalTrials.org ID: NCT 04085679

BACKGROUND

The increasing clinical complexity of older medical patients in industrialized countries, due to multimorbidity, polypharmacy, frailty, disability and social hardship, is challenging for health care systems [Corazza 2019, Mannucci 2018]. Firstly, these patients are often admitted to Emergency Departments (EDs), accounting for 12 to 24% of all ED visits [Samaras 2010]. However, their complex needs are often poorly met in this setting, where the busy, overcrowded environment does not always allow a careful evaluation of the multi-faceted clinical problems of elderly patients [Aminzadeh 2002, Salvi 2007, Jay 2017]. These difficulties not only contribute to ED overcrowding, but they may also lead to inaccurate diagnoses and unrecognized or untreated health problems [Limpawattana 2016]. Older patients furthermore have an up to 5-times-higher risk of ward admission, irrespective of the severity of the clinical problem [Samaras 2010, Salvi 2007, Roberts 2008]. Once admitted, they are far more likely to stay in hospital for more than two weeks [Jay 2017] and are at much greater risk of experiencing complications related to hospital admission [Buurman 2012].

These issues are especially relevant for residents of nursing homes, who exhibit a particularly high risk of hospitalization (greater than 20% per year [Wyman 2010]) and are at high risk of complications during hospitalization, due to frailty, multimorbidity and the possible presence of cognitive impairment.

In the light of these considerations, a number of approaches have been developed designed to reduce the risk of hospitalization in nursing home residents. These are summarized in the very recent systematic review by Santosaputri et al [Santosaputri 2019], which includes quantitative comparative studies of all designs aiming to determine the efficacy of interventions provided by a health professional specializing in geriatric medicine. 16 studies were eligible, of which 6 randomized controlled trials, involving an estimated total of over 7400 patients. The authors of the review categorized 14 intervention programs into three primary approaches (two did not fit in any category):

- Prevention approach (nine studies): Interventions applied in the nursing home to prevent hospitalization of residents, in most cases involving care provided by nurses, physicians, and sometimes allied health personnel. The majority of interventions involved either direct review of patients, telephone (or telemedicine) support, or comprehensive geriatric assessment.
- Emergency department-based hospital avoidance (three studies): interventions targeting nursing home residents presenting to the ED to facilitate early discharge and avoid hospitalization. Programs of this type involved care provided by nursing staff (e.g. intravenous therapy, wound care, catheter management).
- Post-hospital supported discharge (two studies): Interventions designed to support residents following hospital admission. One of the studies evaluated the efficacy of geriatrician and nurse review in the facility and the development of a comprehensive tailored care plan following hospital admission; the other assessed the efficacy of a tailor-made intervention compared to a standardized rehabilitation program following admission due to hip fracture.

Although the majority of the studies reported reductions in hospitalizations (in the form of either ED presentations or hospital admissions), only six obtained statistically significant findings, of which none were RCTs. Unfortunately, the quality of evidence was considered low to moderate, therefore the authors emphasize the need for further, well-designed studies to identify which interventions are effective in reducing hospitalization in the older residents. At our institution, for many years different projects have been carried out to improve care of the elderly, primarily targeting hospital organization, with the main objective to reduce unnecessary, avoidable length of stay (LOS) [Meschi 2012, Caminiti 2013, Meschi 2016]. These efforts benefit in-hospital patients, but are not designed to prevent hospitalizations. Based on literature evidence, and drawing on our long-time experience with elderly care, we hypothesize that a complex intervention delivered in nursing homes, where vulnerable high-risk patients live, involving direct patient care by hospital medical staff with geriatric expertise, may reduce hospitalization of residents.

METHODS

The study is based in the University Hospital of Parma, which has a catchment area of more than 400,000 inhabitants, of whom 22.3% is over 65 years old. It provides the only Emergency service of the district, and it ranks fourth in Italy by number of ED visits (yearly average of over 110,000). The average admission rate of the adult ED population is 18%, of which 65% concern people older than 65.

In the last two decades, the University Hospital of Parma has implemented several innovative initiatives to manage the hospital flow of frail multimorbid patients and their complex needs. These initiatives included bed management to avoid “bed-blockers” [Meschi 2012], physician accountability for the discharge process [Caminiti 2013], and creation of a dedicated hospital unit, organized by intensity of care to anticipate the needs of these patients preserving high performance indices [Meschi 2016]. This unit, called Internal Medicine and Critical Subacute Care Unit, performs over 3,500 urgent admissions of frail multimorbid elderly patients per year, with an average length of stay that in 30% of cases is lower than 3 days [Meschi 2016].

Participating nursing homes are public facilities which ensure the presence of nursing staff 24 hours a day and of a physician at least 4 hours a day (high-intensity care facilities). The possible role of distance to the hospital is considered by including in each group one nursing home located next to the hospital and one located >5 km of distance.

The participating nursing homes are the following:

- C.R.A. “I Tigli” C/O Comprensorio di Villa Parma, Piazzale Fiume 5, Parma (intervention group)
- C.R.A. “Casa degli Anziani”, Via Aldo Moro 2, Collecchio (intervention group)
- C.R.A. “Le Tamerici” C/O Comprensorio di Villa Parma, Piazzale Fiume 5, Parma (control group)
- C.R.A. “Ines Ubaldi”, Via Ravenna 4, Parma (control group)

This study follows a multimethod approach, based on the MRC framework for developing and evaluating complex interventions [Craig 2008], including the development, feasibility assessment, and evaluation phases.

1. Development of the intervention

First, the different types of approaches reported in the literature, described above, were considered. The “prevention approach”, interventions conducted in nursing homes, was chosen as the most suitable strategy to integrate the hospital’s organizational model already in place, as it can target both hospitalization rates and ED overcrowding, allowing to intervene before the person accesses the hospital.

Available evidence also prompted us to opt for a multicomponent approach. In fact, data from qualitative interviews reveal that the decision to transfer residents to hospital may be influenced by different factors, such as staffing and skill mix in the nursing homes, treatment options available in the facility, end-of-life decision-making, and communication and bureaucratic requirements. This multifactorial association means that a multicomponent intervention is likely to be more effective than a single-component intervention [Arendts 2010].

The choice of employing a mobile geriatric specialist service was supported by the positive results obtained by the two controlled studies which examined similar interventions [Schippinger 2012, Diaz-Gegùndez 2011]. Schippinger et al [Schippinger 2012] evaluated a service where a physician did regular and on-call visits intended to provide services otherwise associated with hospitalization. Diaz-Gegùndez et al [Diaz-Gegùndez 2011] evaluated an ambulant team with a nurse and a physician, doing comprehensive geriatric assessments of residents as well as reviewing medications and providing support to staff. Our intervention does not involve a nurse, unlike the Diaz-Gegùndez study, because in the participating facilities nursing staff is available 24 hours a day. Unlike the experience of Schippinger et al, moreover, we chose not to perform periodic visits on site, since routine clinical management and scheduled follow-up is already performed by nursing home physicians.

Finally, medical hospital staff was preferred to community geriatricians, on the assumption that older patients may feel more comfortable being handled by physicians who may have already cared for them at the hospital. Moreover,

hospital staff enables direct patient referral to the ward. Finally, this allows the use of diagnostic technologies available at the hospital, which can be used immediately without the need for hospital admission.

The MMU care model intervention

The model hinges on the strong collaboration between hospital and nursing home staff to provide residents with patient-centered care. It entails a multicomponent intervention which is integrated in standard care and comprises three steps: 1) MMU team activation, 2) on site visit by a team of physicians with geriatric expertise, 3) interdisciplinary care planning (Figure 1).

Step 1: MMU team activation

Patient selection is necessary to ensure that available resources are used for patients who may really benefit. To this end, the nursing home physician contacts by phone the “flow manager”, a skilled internist with strong clinical expertise, organizational attitude and managerial training, during the 8 a.m.-6 p.m. time frame, Monday to Friday. The phone consultation is reported on a form containing the description of the patient’s clinical condition and a summary of the conversation. The form also indicates which decision was reached among the following 6 not mutually exclusive options:

- a) The patient can be managed by nursing home staff, therapeutic advice is provided by phone
- b) Remote reassessment is scheduled after a number of hours agreed upon by the team
- c) The MMU team is dispatched for evaluation, treatment and stabilization on site
- d) A significant change in vital parameters is observed which requires immediate activation of emergency services
- e) Direct hospital admission is considered necessary
- f) Ambulatory outpatient visits or tests are planned

Step 2: on site visit by a team of physicians with geriatric expertise

Visits at the nursing home are performed by two members of the MMU team: an expert hospital physician chosen on a case-by-case basis among the clinical staff of the Internal Medicine and Critical Subacute Care Unit, which comprises internists, gastroenterologists, geriatricians, specialists in clinical nutrition, depending on the disease or clinical problem that must be treated, and a specifically trained resident in Emergency Medicine.

The team is provided with a car to reach the nursing homes, a portable ultrasound system, and an essential set of drugs and medical devices useful in an emergency setting. The ultrasound system is equipped with three probes (convex, linear, and phased-array) for performing thoraco-pulmonary, cardiac, vascular, abdominal and soft tissue ultrasound, when required. Available drugs include those that can be administered intravenously for treating urgent conditions (e.g. loop diuretics, steroids, fluids, antibiotics). Devices include central and peripheral venous lines, nasogastric and rectal tubes and bladder catheters. Blood tests can also be performed.

Table 1 shows possible clinical scenarios which may require MMU team activation, and possible decisions.

Step 3: interdisciplinary care planning

Based on the results of the visit and of any performed investigations, the MMU team formulates personalized advice and referrals, and discusses these with the nursing home physician. If stabilization on site is not deemed possible, the MMU team plans a direct admission to the Internal Medicine and Critical Subacute Care Unit, thus avoiding ED access. The planning and the final outcome of the intervention are recorded in the second part of the form.

2. Feasibility assessment

A pilot phase of 5 months (December 2018-April 2019) was conducted in two nursing homes in order to look at feasibility of the MMU care Model described above. Before the intervention was introduced, meetings were held with nursing home staff to agree on activation modalities.

In this period, 99 phone calls were received, of which 84 required MMU team onsite visits, and 15 were managed with remote consultancy. Of the latter, 3 required direct admission after remote phone consultancy. Only 4 of the 84 patients visited onsite required direct admission. One patient was sent to the ED for massive intestinal bleeding (Figure 2).

This phase demonstrated the feasibility of the intervention, and did not highlight any need for modifications.

3. Evaluation phase

Aim and objectives

The study aim is to verify the effects of the implementation of the MMU care model tested in the pilot phase.

Primary objective is to verify reduction of unplanned hospitalization rates in the nursing homes of the intervention group compared to the nursing homes in the control group. Secondary objectives are to measure the effects of the intervention in terms of mortality, health service use, and costs.

Study Design

This study is a prospective, pragmatic, multicenter, quasi-experimental study (sequential design with two cohorts), in which usual nursing home care is compared to care provided by applying the MMU model.

Study Population

All residents of the participating nursing homes are eligible, regardless of their clinical status. Residents who do not provide informed consent will be excluded.

Usual Care

Patients in the control cohort receive usual care, which means the actions to take are decided by the nursing home staff. Generally, this implies that patients who are clinically unstable, or require urgent instrumental tests, will be sent to the ED.

Measures

Baseline variables

Demographic data on gender and age are collected by chart review.

Outcome variables

The primary outcome is hospitalization rate, considering at the numerator all unplanned admissions occurred during a 1-year period, and at the denominator the sum of the person-time of the at risk population (days of stay at the nursing home). For the intervention group, the numerator corresponds to options d) and e) defined in “Step 1: MMU team activation”.

Secondary outcomes:

- Crude all-cause Death Rate (CDR): the number of deaths *during a* 1-year period on person-time of the at risk population
- Hospital Mortality rate: the frequency of patients who die while in the hospital (death rate/1000)

- Length of stay (LOS): the duration of a single episode of hospitalization. Inpatient days are calculated by subtracting day of admission from day of discharge.
- Adverse events or complications: frequency of events occurred within 48 hours from MMU team activation and subsequent patient stabilization, for which hospital access becomes necessary.
- Costs analysis, comparing the cost differences in the two groups

Data Collection

Patient demographic and clinical characteristics are collected at baseline to describe the study population and determine factors associated with hospital rate. Participants' files and electronic data are stored securely at the study site (e.g. locked area, password protected hard- and software). Data integrity will be scrutinized with several strategies (e.g. valid values, range checks, consistency checks). Patient data are only identifiable with the unique participant's number. Personal information will be collected and saved in a separate file (on a different server) which can only be accessed by the Principal Investigator (PI). This information will be used by the PI to retrieve data on any hospital admissions (length of stay, in-hospital death ...) from administrative databases (discharge summaries, ED data, Death Registry). Residents' identification data will be deleted once the study is completed, making the dataset anonymous. All study protocol authors will have access to the anonymous dataset.

Cost analysis

We will identify the changes in net costs associated with one-year exposure to the intervention, consisting in the induced costs due to incremental resource inputs for carrying out the intervention and hospital health service utilization costs. Staffing costs will be calculated considering the time spent by the professionals involved in the intervention. Non-staff running costs include expenses of MMU staff travelling to and from the nursing home. The health service utilization costs will be identified based on the Diagnosis Related Group (DRG) system.

Statistical Methodology

Sample size calculation

The number of subjects to include was estimated using the findings of Diaz-Gegundez et al [Diaz 2011], who performed a large quasi-experimental trial. Thus, considering 56 cases vs 32 cases per 100 residents, and using a 2-sided, large-samples z-test of the Poisson incidence rate difference at a significance level of 0.05, and with a power of 0.90, overall 338 residents should be enrolled.

Statistical analysis

Descriptive statistics will be used to summarize patient populations and will be presented as means and standard deviations (SD) when normally distributed, or as medians and interquartile ranges (IQR).

For the primary analysis we will use Poisson regression with robust standard errors (SEs) to evaluate relative differences in hospital rates among our two cohorts while adjusting for demographic characteristics.

Concerning the secondary outcomes, the following analyses will be performed:

- Rates will be compared considering the quotient between the intervention and control groups
- A lognormal model will be used to compare in-hospital LOS.
- Chi square tests will be conducted for categorical data as adverse events or complications
- For costs, we will use the following equations to summarize the annual net costs associated with the implementation of the intervention. Any costs with negative values mean "savings" and any costs with positive values mean "losses". Net costs = A... (intervention costs) + B (Costs for differences in hospital health service utilization) where: A= intervention: staffing costs+intervention: non- staff costs and B= Costs

for differences in inpatient care utilization. Therefore, the net costs arising from one-year implementation of the intervention as compared with the current practice will be obtained, where a negative value of net costs represents “cost-saving” and a positive value represents “not cost-saving”

The demographic and clinical variables which influence the outcome with a p value < 0.20 in the univariate analysis will be included in the Poisson regression model.

The analyses will be performed using SAS 8.2 (SAS Institute, Cary, NC, USA) and STATA-SE 11 (Stata Corp LP, College Station, TX, USA).

Data monitoring

Since this is a non-profit study promoted by the University Hospital of Parma, study monitoring is in charge of trained staff of the hospital’s Research and Innovation Unit, as set forth in current legislation (Ministerial Decrees 211/2003 and 15/11/2011).

Ethical and regulatory aspects

The study will be conducted in compliance with the principles of the revision of the Helsinki Declaration and by current legislation on scientific research.

The protocol and the patient informed consent form will be submitted to the competent Ethics Committee for approval, in accordance with Italian current norms. The study will be initiated prior authorization from the legal representative of the center in which it is conducted.

Informed consent

This study does not entail any experimental pharmacological treatment, or changes in the diagnostic-therapeutic pathway. Eligible patients will be asked to give consent to handling of their personal data in writing. The consent form will be dated and signed by the patient and by the investigator, authorized according to norms of the local Ethics Committee.

A copy of the signed informed consent form shall be given to the patient, and the original shall be retained by the investigator as part of the study documentation. Informed consent is required for all patients, also in the control group. Informed consents are obtained by nursing home physicians, who are in charge of enrolment. In the case of persons incapable of giving informed consent according to the investigator (such as patients with dementia), consent will be sought from a legal representative.

If a patient wishes to discontinue his/her participation in the study, it is the responsibility of the investigator to ensure that no further data regarding the person’s health condition shall be collected. All collected data will be used in the final analysis.

Confidentiality

All data collected, handled and stored for the purpose of this study will be kept confidential at any time and will be securely stored, as required in GCP guidelines and in current privacy legislation. All data will be gathered anonymously and handled by the project team in charge of analysis and management.

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3 Patients will only be identifiable by the clinical staff of the center where the patient was recruited. All data collected
4 anonymously will be checked and analyzed at the Research and Innovation Unit of the University Hospital of Parma,
5 responsible for the analysis and correct keeping of the archive.
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10 **Study organization and responsibilities**

11 **Scientific Committee (SC)**

12 It performs overall study supervision and strategic control through periodic meetings, in which the coordination
13 team informs the Committee on the project's progress, on any observed problems, and on possible solutions. It is
14 responsible to decide whether a process should be halted or modified. It ensures that results are published on peer-
15 reviewed journals within one year after study completion.
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19 **Principal Investigator (PI)**

20 The PI is responsible for the protection of patients' rights and for the integrity of the research. The PI must keep an
21 updated list of appropriately qualified professionals, to whom he can delegate important activities relating to the
22 study, and for whom he must provide the necessary training. The PI shall ensure that no deviations from the protocol
23 occur, and that the protocol is not modified in any way without prior documented Ethics Committee review and
24 approval. Before study initiation, the PI must obtain authorization from the Managing Director of the University
25 Hospital of Parma to conduct the trial in compliance with the protocol.
26
27
28

29 The PI must guarantee precision, completeness, readability and timeliness of data reported in the collection forms
30 (CRFs) and in all required reports. Data reported in the eCRF, retrieved from original documents, must agree with
31 those indicated in the reports; any discrepancies shall be verified and explained.
32

33 The PI will prepare a folder (Investigator's File, IF) containing: all study documentation approved by the Ethics
34 Committee, including amendments and minutes, signed agreements, curricula vitae of the PI and other
35 investigators/delegates, register of enrolled subjects, list of subject identification codes.
36

37 The PI is responsible for the retention of documents essential to the conduction of the clinical trial in the
38 Investigator's Study File, for the time required by relevant legislation, and must adopt all necessary measures to
39 prevent the accidental or premature destruction of these documents.
40

41 At study completion, the PI shall immediately inform the institutions involved in the trial and the competent Ethics
42 Committee, providing them a detailed report on conduction and results.
43

44 **Clinical Investigators (CIs)**

45 They are the physicians comprising the MMU and those working in participating nursing homes. The latter perform
46 patient screening and enrolment, and are in charge of the informed consent obtainment process. The informed
47 consent must be acquired and documented in accordance with current applicable norms and must adhere to GCP
48 and ethical principles rooted in the Helsinki Declaration. Patients shall be provided with exhaustive information on
49 all aspects relating to the study, including modalities and duration, and collection of necessary data.
50
51

52 **Trial Statistician (TS)**

53 The TS develops the eCRF equipped with automatic checks and tracking of corrections made by the user and user
54 identification, ensuring the presence of strictly necessary variables. The TS conducts statistical analyses required to
55 verify study end points, after checking for data quality (quality assurance and quality control) and after defining the
56 Statistical Analysis Plan (SAP). The TS prepares the tables and graphs needed to summarize and publish results, and
57 contributes to the drafting of the paper, by providing indications concerning analysis interpretation, and the
58 presence of any biases and methodological limitations.
59
60

Retaining of original documents

The medical staff of the nursing homes shall retain the original copies of the informed consents, dated and signed by the patient and the physician. MMU medical staff will be responsible for storing the case report forms of each enrolled patient.

Publication policy

The Promoter of the study is the University Hospital of Parma, which therefore maintains ownership of data. The Research and Innovation Unit is responsible for data management and statistical analysis. Findings will be published under the responsibility of the study's SC and prior verification of the Promoter (according to Ministerial Decree 17/12/2004).

Authorship will be determined by unanimous consensus of the SC, in compliance with International Committee of Medical Journal Editors (ICMJE) recommendations, which indicate the following four criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Individual researchers wishing to perform additional analyses to include in publications or conference presentations shall submit a request to the SC, for evaluation and authorization. A copy of any presentation, manuscript or abstract must be sent to the SC before dissemination.

Protocol modifications

All amendments made to the protocol shall be submitted to the AVEN Ethics Committee. Amendments shall not be implemented without prior ethical approval. Modifications to the protocol which only concern administrative or logistical aspects of the study will need to be communicated to the Ethics Committee. Any violations of the protocol shall be reflected in the data reported in the eCRF and in the original documents, and original documents shall describe such violations, as well as the circumstances that made them necessary.

Study duration

Overall expected duration is 18 months, with study initiation presumably in November 2019 and completion in April 2021.

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TABLE 1

Overview of possible expected clinical situations for which a Multidisciplinary Mobile Unit consultation may be activated, and possible management.

Clinical situation	Clinical question	Mobile Unit Intervention	Disposition
Dyspnea of unknown origin	Pulmonary? Cardiac? Embolism? Other causes?	Chest and Abdomen Ultrasound. Arterial Gas sample, ECG	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Abdominal pain	Gallbladder stones? Cholecystitis? Renal colic? Diverticular disease? Urinary retention? Faecal impaction? Peritonitis? Ascites? Acute/subacute Hernia?	Abdomen ultrasound, basic blood tests	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Hematuria	UTI? Catheter dysfunction? Bladder polyps? Stones?	Abdomen ultrasound, Bladder lavage, Catheter (re-)positioning	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Psychomotor agitation in previously stable dementia	Inadequate therapy? Emerging internistic problem? Other	CGA, Neurogeriatric visit, exclusion of internistic emerging problem, ECG, Thoracic&abdominal US	Appropriate diagnosis and treatment on site.
Fever	Origin?	Thoracic&abdominal US, basic blood test	Excluding common differential diagnosis
Absence of peripheral veins for drugs or nutrients infusion	How to find adequate venous access	US guided Central venous catheter or PICC or peripheral access	Securing patient
Monolateral leg edema	DVT? Erysipelas? Trauma?	Venous and soft tissues ultrasound	Appropriate diagnosis and treatment on site.

1 2 3 4 5 6 7 8	Terminal illness	Palliation strategy? How to get symptoms relief?	CGA. Multidisciplinary assessment. Positioning of drains (eg abdominal drainage for ascites). Interview with relatives / caregivers and GP for sharing strategies	Appropriate management.
9 10 11 12 13 14	Ultrasound exam in a patient who can be transported with difficulty	GP's question	Abdominal, cardiac, arterial, thyroid, neck ultrasound	Appropriate assessment

15 ECG = Electrocardiogram; UTI = Urinary Tract Infection; CGA = Comprehensive Geriatric Assessment; US = Ultrasound; PICC = Peripherally-Inserted Central Venous Catheter;
 16 DVT = Deep Vein Thrombosis; GP = General Practitioner.
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For peer review only

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Figure 1. Description of the intervention of MMU Team

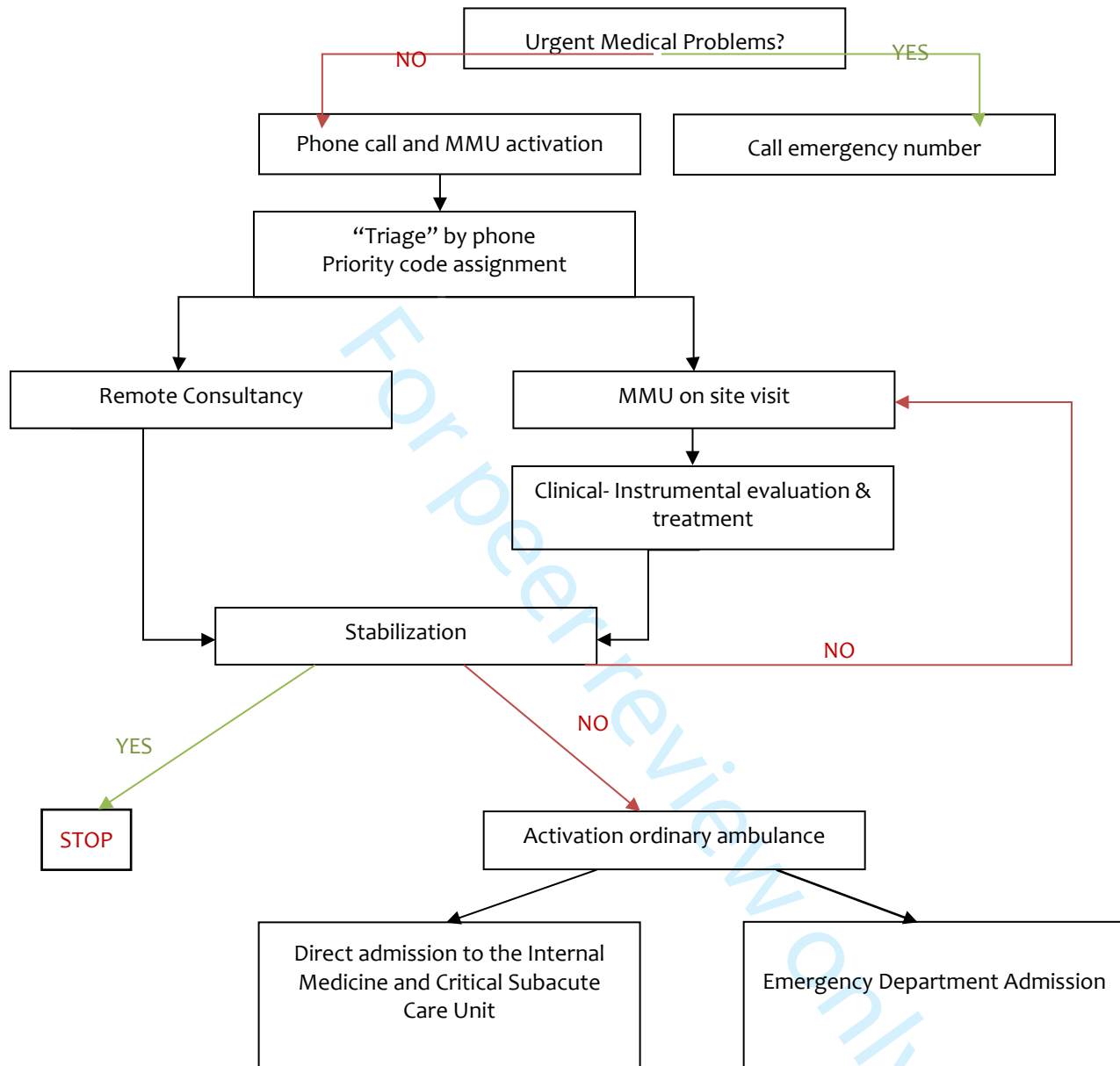
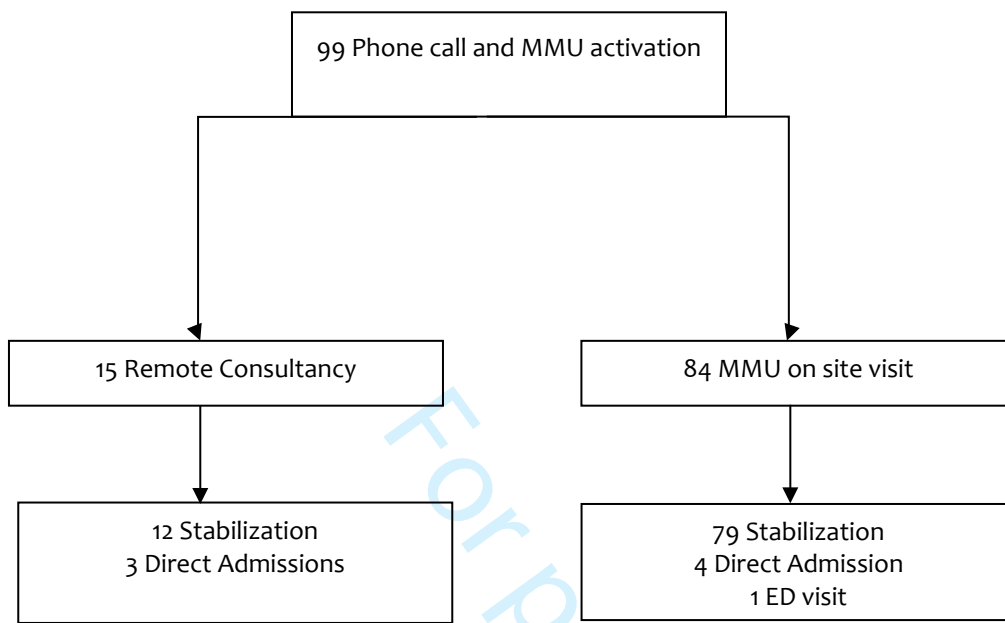


Figure 2. Results of pilot phase



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Parma, 25/7/2019

Undersigned,

The Principal Investigator
Prof. Tiziana Meschi

For peer review only

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

	Reporting Item	Page Number
Administrative information		
Title	#1 Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

1	Trial registration	#2a	Trial identifier and registry name. If not yet	2, end of abstract
2			registered, name of intended registry	
3				
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5				
6	Trial registration:	#2b	All items from the World Health Organization	2
7				
8	data set		Trial Registration Data Set	
9				
10				
11				
12	Protocol version	#3	Date and version identifier	Supplemental
13				
14				Material
15				
16				
17	Funding	#4	Sources and types of financial, material, and	14
18			other support	
19				
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21				
22				
23	Roles and	#5a	Names, affiliations, and roles of protocol	1, 14
24				
25	responsibilities:		contributors	
26				
27	contributorship			
28				
29				
30	Roles and	#5b	Name and contact information for the trial	N/A (page 14)
31				
32	responsibilities:		sponsor	
33				
34	sponsor contact			
35				
36				
37	information			
38				
39				
40	Roles and	#5c	Role of study sponsor and funders, if any, in	N/A (page 13)
41				
42	responsibilities:		study design; collection, management, analysis,	
43				
44	sponsor and funder		and interpretation of data; writing of the report;	
45				
46				
47			and the decision to submit the report for	
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49			publication, including whether they will have	
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51			ultimate authority over any of these activities	
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1	Roles and	#5d	Composition, roles, and responsibilities of the	13
2				
3	responsibilities:		coordinating centre, steering committee,	
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5	committees		endpoint adjudication committee, data	
6				
7			management team, and other individuals or	
8				
9			groups overseeing the trial, if applicable (see	
10				
11			Item 21a for data monitoring committee)	
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15	Introduction			
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18	Background and	#6a	Description of research question and	4-5
19				
20	rationale		justification for undertaking the trial, including	
21				
22			summary of relevant studies (published and	
23				
24			unpublished) examining benefits and harms for	
25				
26			each intervention	
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31	Background and	#6b	Explanation for choice of comparators	4-5
32				
33	rationale: choice of			
34				
35	comparators			
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37				
38	Objectives	#7	Specific objectives or hypotheses	6, 9
39				
40				
41	Trial design	#8	Description of trial design including type of trial	9-10
42				
43			(eg, parallel group, crossover, factorial, single	
44				
45			group), allocation ratio, and framework (eg,	
46				
47			superiority, equivalence, non-inferiority,	
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49			exploratory)	
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54	Methods:			
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56	Participants,			
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1 **interventions, and**

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3 **outcomes**

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6	Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
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16	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
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25	Interventions:	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9, 10
26	description			
27				
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33	Interventions:	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A (complex intervention on organization of care)
34	modifications			
35				
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45	Interventions:	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A (the intervention concerns organization of care in nursing homes)
46	adherence			
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1	Interventions:	#11d	Relevant concomitant care and interventions	7-10
2				
3	concomitant care		that are permitted or prohibited during the trial	
4				
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6	Outcomes	#12	Primary, secondary, and other outcomes,	10
7				
8			including the specific measurement variable	
9				
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11			(eg, systolic blood pressure), analysis metric	
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13			(eg, change from baseline, final value, time to	
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15			event), method of aggregation (eg, median,	
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17			proportion), and time point for each outcome.	
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19			Explanation of the clinical relevance of chosen	
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21			efficacy and harm outcomes is strongly	
22				
23			recommended	
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28	Participant timeline	#13	Time schedule of enrolment, interventions	11
29				
30			(including any run-ins and washouts),	
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32			assessments, and visits for participants. A	
33				
34			schematic diagram is highly recommended (see	
35				
36			Figure)	
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40	Sample size	#14	Estimated number of participants needed to	11
41				
42			achieve study objectives and how it was	
43				
44			determined, including clinical and statistical	
45				
46			assumptions supporting any sample size	
47				
48			calculations	
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52	Recruitment	#15	Strategies for achieving adequate participant	N/A (all residents in
53				participating nursing
54			enrolment to reach target sample size	homes will be
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eligible for the
study)

Methods:

**Assignment of
interventions (for
controlled trials)**

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A (quasi- experimental study design on organization of care)
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A (quasi- experimental study design on organization of care)
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A (quasi- experimental study design on organization of care)

1 2 3 4 5 6 7 8 9 10 11 12	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A (quasi-experimental study design on organization of care)
13 14 15 16 17 18 19 20 21 22 23 24	Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A (quasi-experimental study design on organization of care)
25 26 27 28 29 30 31 32 33 34	Methods: Data collection, management, and analysis			
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-11

1	Data collection	#18b	Plans to promote participant retention and	N/A (quasi-
2				
3	plan: retention		complete follow-up, including list of any	experimental study
4				
5			outcome data to be collected for participants	design on
6				
7			who discontinue or deviate from intervention	organization of
8				
9			protocols	care)
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13	Data management	#19	Plans for data entry, coding, security, and	11, 13
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15			storage, including any related processes to	
16				
17			promote data quality (eg, double data entry;	
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19			range checks for data values). Reference to	
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21			where details of data management procedures	
22				
23			can be found, if not in the protocol	
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28	Statistics:	#20a	Statistical methods for analysing primary and	12
29				
30	outcomes		secondary outcomes. Reference to where other	
31				
32			details of the statistical analysis plan can be	
33				
34			found, if not in the protocol	
35				
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38	Statistics: additional	#20b	Methods for any additional analyses (eg,	12
39				
40	analyses		subgroup and adjusted analyses)	
41				
42				
43	Statistics: analysis	#20c	Definition of analysis population relating to	N/A due to
44				
45	population and		protocol non-adherence (eg, as randomised	particular study
46				
47	missing data		analysis), and any statistical methods to handle	design
48				
49			missing data (eg, multiple imputation)	
50				
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52				

Methods:

Monitoring

1	Data monitoring:	#21a	Composition of data monitoring committee	13
2			(DMC); summary of its role and reporting	
3	formal committee		structure; statement of whether it is	
4			independent from the sponsor and competing	
5			interests; and reference to where further details	
6			about its charter can be found, if not in the	
7			protocol. Alternatively, an explanation of why a	
8			DMC is not needed	
9				
10	Data monitoring:	#21b	Description of any interim analyses and	13
11			stopping guidelines, including who will have	
12	interim analysis		access to these interim results and make the	
13			final decision to terminate the trial	
14				
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20	Harms	#22	Plans for collecting, assessing, reporting, and	N/A due to
21			managing solicited and spontaneously reported	particular study
22			adverse events and other unintended effects of	design
23			trial interventions or trial conduct	
24				
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30	Auditing	#23	Frequency and procedures for auditing trial	N/A due to
31			conduct, if any, and whether the process will be	particular study
32			independent from investigators and the sponsor	design
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40	Ethics and			
41	dissemination			
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53	Research ethics	#24	Plans for seeking research ethics committee /	12-13
54			institutional review board (REC / IRB) approval	
55	approval			
56				
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1	Protocol	#25	Plans for communicating important protocol	12-13 +
2				
3	amendments		modifications (eg, changes to eligibility criteria,	supplemental
4			outcomes, analyses) to relevant parties (eg,	material
5			investigators, REC / IRBs, trial participants, trial	
6			registries, journals, regulators)	
7				
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13	Consent or assent	#26a	Who will obtain informed consent or assent	12-13 +
14			from potential trial participants or authorised	supplemental
15			surrogates, and how (see Item 32)	material
16				
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21	Consent or assent:	#26b	Additional consent provisions for collection and	12-13 +
22	ancillary studies		use of participant data and biological	supplemental
23			specimens in ancillary studies, if applicable	material
24				
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28	Confidentiality	#27	How personal information about potential and	12-13 +
29			enrolled participants will be collected, shared,	supplemental
30			and maintained in order to protect	material
31			confidentiality before, during, and after the trial	
32				
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38	Declaration of	#28	Financial and other competing interests for	14
39	interests		principal investigators for the overall trial and	
40			each study site	
41				
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46	Data access	#29	Statement of who will have access to the final	12-13 +
47			trial dataset, and disclosure of contractual	supplemental
48			agreements that limit such access for	material
49			investigators	
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1	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial	N/A due to
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3	trial care		care, and for compensation to those who suffer	particular study
4				
5			harm from trial participation	design
6				
7				
8	Dissemination	#31a	Plans for investigators and sponsor to	13 + supplemental
9				
10	policy: trial results		communicate trial results to participants,	material
11				
12			healthcare professionals, the public, and other	
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14			relevant groups (eg, via publication, reporting in	
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16			results databases, or other data sharing	
17				
18			arrangements), including any publication	
19				
20			restrictions	
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25	Dissemination	#31b	Authorship eligibility guidelines and any	Supplemental
26				
27	policy: authorship		intended use of professional writers	material
28				
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31	Dissemination	#31c	Plans, if any, for granting public access to the	Supplemental
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33	policy: reproducible		full protocol, participant-level dataset, and	material
34				
35	research		statistical code	
36				
37				
38	Appendices			
39				
40				
41	Informed consent	#32	Model consent form and other related	Supplemental
42				
43	materials		documentation given to participants and	material
44				
45			authorised surrogates	
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49	Biological	#33	Plans for collection, laboratory evaluation, and	N/A due to study
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51	specimens		storage of biological specimens for genetic or	design
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53			molecular analysis in the current trial and for	
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55			future use in ancillary studies, if applicable	
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3 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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11 **NOTE: The original protocol approved by the competent Ethics Committee (in English language) has**
12 **been uploaded as Supplemental Material.**
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BMJ Open

Implementation of a strategy involving a multidisciplinary mobile unit team to prevent hospital admission in nursing home residents: protocol of a quasi-experimental study (MMU-1 Study)

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1 **Implementation of a strategy involving a multidisciplinary mobile unit team to prevent hospital**
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3 **admission in nursing home residents: protocol of a quasi-experimental study (MMU-1 Study)**
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6 3

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Running Title: Multidisciplinary mobile unit intervention for nursing homes

1 **ABSTRACT**

2
3 **Introduction-** Nursing home residents represent a particularly vulnerable population experiencing high risk
4
5 of unplanned hospital admissions, but few interventions have proved effective in reducing this risk. The aim
6
7 of this research will be to verify the effects of a hospital-based multidisciplinary mobile unit (MMU) team
8
9 intervention delivering urgent care to nursing home residents directly at their bedside.

10
11 **Methods and analysis-** Four nursing homes based in the Parma province, in Northern Italy, will be involved
12
13 in this prospective, pragmatic, multicenter, 18-month quasi-experimental study (sequential design with two
14
15 cohorts). The residents of two nursing homes will receive the MMU team care intervention. In case of urgent
16
17 care needs, the nursing home physician will contact the hospital physician responsible for the MMU team by
18
19 phone. The case will be triaged as a) manageable by phone advice, b) requiring urgent assessment by the MMU
20
21 team or c) requiring immediate ED referral. MMU team is composed of one senior physician and one
22
23 Emergency-Medicine resident chosen within the staff of Internal Medicine and Critical Subacute Care Unit of
24
25 Parma University-Hospital, usually with different specialty background, and equipped with portable
26
27 ultrasound, set of drugs and devices useful in urgency. The MMU visits patients in nursing homes, with the
28
29 mission to stabilize clinical conditions and avoid hospital admission. Residents of the other two nursing homes
30
31 will receive usual care, i.e. ED referral in every case of urgency. Study endpoints include unplanned hospital
32
33 admissions (primary), crude all-cause mortality, hospital mortality, length of stay and healthcare-related costs
34
35 (secondary).

36
37 **Ethics and dissemination-** The study protocol was approved by the Ethics Committee of Area Vasta Emilia
38
39 Nord. Informed consent will be collected from patients or their legal representatives. The results will be
40
41 actively disseminated through peer-reviewed journals and conference presentations, in compliance with the
42
43 Italian law.

44
45 **Registration ID-** ClinicalTrials.gov NCT 04085679

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52 **Key words:** multimorbidity; geriatrics; hospitalization; multidisciplinary care; hospital-community
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54 partnership

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1 STRENGTHS AND LIMITATIONS OF THIS STUDY

- 2 ✓ This study will explore the effectiveness of a complex intervention focused on the avoidance of
- 3 hospital admissions for nursing home residents, with a strong hospital-community partnership.
- 4 ✓ The study intervention consists in bringing specialist hospital care directly at the bedside of nursing
- 5 home residents, an innovative approach not previously described in the scientific literature.
- 6 ✓ The intervention has been developed considering the organization of the Italian healthcare system, but
- 7 is reproducible and applicable in other settings.
- 8 ✓ Due to ethical concerns and the complex nature of the intervention, randomization of participants is
- 9 not possible.

For peer review only

1 INTRODUCTION

2 The increasing clinical complexity of older medical patients, due to multimorbidity, polypharmacy, frailty,
3 disability and social hardship, is challenging for health care systems.^{1 2} These characteristics are emphasized
4 in nursing home residents, who experience a particularly high risk of Emergency Department (ED) visits and
5 hospitalization (greater than 20% per year).³⁻⁸ In the ED, these patients may experience misdiagnoses and
6 undertreatment, due to their clinical complexity and atypical presentation of acute illness, and substantially
7 contribute to the overcrowding phenomenon.^{4 5 9-11} Once admitted to wards, they are also far more likely to
8 have long stays (>2 weeks)⁹ and experience hospital-related complications.¹²

9 In the light of these considerations, confirmed by large cohort studies conducted in the United States and
10 Canada,^{7 8} a number of approaches have been developed designed to reduce the risk of hospitalization in
11 nursing home residents. These are summarized in the recent systematic review by Santosaputri et al,¹³ which
12 includes quantitative comparative studies of all designs aiming to determine the efficacy of interventions
13 provided by a health professional with specialization in geriatric medicine. Sixteen studies were eligible, of
14 which 6 randomized controlled trials, involving an estimated total of over 7400 patients. The authors of the
15 review categorized 14 intervention programs into three primary approaches (two did not fit in any category):

- 16 - Prevention approach (nine studies): Interventions applied in the nursing home to prevent
17 hospitalization of residents, in most cases involving care provided by nurses, physicians, and
18 sometimes allied health personnel. The majority of interventions involved either direct review of
19 patients, telephone (or telemedicine) support, or comprehensive geriatric assessment.
- 20 - Emergency department-based hospital avoidance (three studies): interventions targeting nursing home
21 residents presenting to the ED to facilitate early discharge and avoid hospitalization. Programs of this
22 type involved care provided by nursing staff (e.g. intravenous therapy, wound care, catheter
23 management).
- 24 - Post-hospital supported discharge (two studies): Interventions designed to support residents in the care
25 transition from the hospital to nursing home, to prevent readmissions, including geriatrician and nurse
26 review in the facility and standardized rehabilitation programs.

27 Although the majority of the studies reported reductions in hospitalizations (in the form of either ED
28 presentations or hospital admissions), only six, with different designs and interventions, obtained statistically
29 significant findings.¹⁴⁻¹⁹ Two of these studies, with a retrospective design, involved delivery of routine care to

1 nursing home residents by hospital-based nursing staff, with the possibility of obtaining support from a
2 geriatrician in case of urgent situations.¹⁴⁻¹⁵ In another prospective quasi-experimental study, a team including
3 a geriatrician and specialized nurses supported the nursing home physician in delivering routine care and in
4 managing urgent clinical situations.¹⁶ The remaining three studies, all with prospective quasi-experimental
5 design, were more focused on selected clinical scenarios, involving advice and education by ED staff to nursing
6 home personnel after ED admission of residents,¹⁷ hospital nurse visits in the nursing home to implement
7 strategies of delirium prevention,¹⁸ and rehabilitation intervention delivered by a geriatric orthopedic team to
8 residents with hip fracture.¹⁹

9 Unfortunately, the quality of evidence was considered low to moderate, therefore further, well-designed studies
10 are needed to identify which interventions are effective in reducing hospitalization in the older residents.¹³ The
11 interventions performed in the existing studies were also mainly focused on routine care, while a prompt and
12 correct management of urgent situations and acute/subacute conditions may be of paramount importance for
13 avoiding ED admissions in nursing home residents. Namely, interventions delivering urgent care with a
14 multidisciplinary approach, based not only on geriatric expertise but also on the capacity of performing first
15 line diagnostic examinations, such as ultrasonography, and basic invasive procedures, such as central venous
16 line or nasogastric tube insertion, have a great potential of being successful in reducing ED visits, but have not
17 been adequately investigated to date.

18 At our institution, different projects have been carried out for many years to improve care of the elderly,
19 primarily targeting hospital organization, with the main objective to reduce unnecessary, avoidable length of
20 stay (LOS).²⁰⁻²² These efforts benefit in-hospital patients, but are not designed to prevent hospitalizations. In
21 this framework, based on literature evidence, best current knowledge and long-time experience with elderly
22 care developed at our university-hospital, we hypothesize that a complex intervention delivered in nursing
23 homes, where vulnerable high-risk patients live, involving direct patient care by hospital medical staff with
24 multidisciplinary approach grounded on geriatric expertise, may reduce hospitalization of residents.

25 26 **METHODS AND ANALYSIS**

27 **Study setting**

28 The study is based in the University Hospital of Parma, which has a catchment area of more than 400,000
29 inhabitants, of whom 22.3% is over 65 years old. It provides the only Emergency service of the district, and it

1 ranks fourth in Italy by number of ED visits (yearly average of over 110,000). The average admission rate of
2 the adult ED population is 18%, of which 65% concern people older than 65.

3 In the last two decades, the University Hospital of Parma has implemented several innovative initiatives to
4 manage the hospital flow of frail multimorbid patients and their complex needs. These initiatives included bed
5 management to avoid “bed-blockers”,²⁰ physician accountability for the discharge process,²¹ and creation of a
6 dedicated hospital unit, organized by intensity of care to anticipate the needs of these patients preserving high
7 performance indices.²² The MMU team will be based in this unit, called Internal Medicine and Critical
8 Subacute Care.

9 Nursing homes participating in the study are public facilities of similar size (90-100 residents) which ensure
10 the presence of nursing staff 24 hours a day and of a physician at least 4 hours a day (high-intensity care
11 facilities), in compliance with the care standards set by the Local Health Authority. No staff member is shared
12 among the participating nursing homes. The possible role of distance to the hospital is considered by including
13 in each group one nursing home located next to the hospital and one located at a distance of >5 km.

14 The participating nursing homes are the following CRAs (Casa Residenza Anziani):

- 15 - C.R.A. “I Tigli” Parma (intervention group)
- 16 - C.R.A. “Casa degli Anziani”, Collecchio (intervention group)
- 17 - C.R.A. “Le Tamerici” Parma (control group)
- 18 - C.R.A. “Ines Ubaldi”, Parma (control group)

19 This study follows a multimethod approach, based on the Medical Research Council framework for developing
20 and evaluating complex interventions,²³ including the development, feasibility assessment, and evaluation
21 phases.

22 **Development of the intervention**

23 First, the different types of approaches reported in the literature, described above, were considered.¹³ The
24 “prevention approach”, interventions conducted in nursing homes, was chosen as the most suitable strategy to
25 integrate the hospital’s organizational model already in place, as it can target both hospitalization rates and ED
26 overcrowding, allowing to intervene before the person accesses the hospital.

27 Available evidence also prompted us to opt for a multicomponent approach. In fact, the current literature,
28 mainly based on qualitative interviews with nursing home staff members in different countries, suggests that
29

1 the decision to transfer residents to hospital may be influenced by different factors, such as staffing and skill
2
3 2 mix in the nursing homes, treatment options available in the facility, end-of-life decision-making, and
4
5 3 communication and bureaucratic requirements.²⁴ This multifactorial association means that a multicomponent
6
7 4 intervention is likely to be more effective than a single-component intervention.²⁵

9
10 5 Based on the Schippinger¹⁶ and Diaz-Gegundez²⁶ studies, we created a mobile physician service. Unlike those
11
12 6 studies, we did not involve a nurse, because the participating facilities have nursing staff available 24 hours a
13
14 7 day, and we used medical hospital staff because routine clinical management and scheduled follow-up
15
16 8 evaluations are already performed by nursing home physicians during their office hours.

17
18 9 Finally, medical hospital staff was preferred to community geriatricians, on the assumption that older patients
19
20 10 may feel more comfortable being handled by physicians who may have already cared for them at the hospital.
21
22 11 Moreover, hospital staff enables direct patient referral to the ward. Finally, this allows the use of diagnostic
23
24 12 technologies available at the hospital, which can be used immediately without the need for hospital admission.
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28 29 14 **Description of the intervention**

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31 15 The model hinges on the strong collaboration between hospital and nursing home staff to provide residents
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33 16 with patient-centered care. It entails a multicomponent intervention which is integrated in standard care and
34
35 17 comprises three steps: 1) MMU team activation, 2) on site visit by a team of physicians with geriatric expertise,
36
37 18 3) interdisciplinary care planning (Figure 1).
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39 19

40 41 20 *Step 1: MMU team activation*

42
43 21 Patient selection is necessary to ensure that available resources are used for patients who may really benefit.
44
45 22 To this end, the nursing home physician contacts by phone the “flow manager”, a skilled internist with strong
46
47 23 clinical expertise, organizational attitude and managerial training, during the 8 a.m.-6 p.m. time frame, Monday
48
49 24 to Friday. The phone consultation is reported on a form containing the description of the patient’s clinical
50
51 25 condition and a summary of the conversation. The form also indicates which decision was reached among the
52
53 26 following six not mutually exclusive options:

- 54 26
- 55
- 56 27 a) The patient can be managed by nursing home staff, therapeutic advice is provided by phone
- 57
- 58 28 b) Remote reassessment is scheduled after a number of hours agreed upon by the team
- 59
- 60 29 c) The MMU team is dispatched for evaluation, treatment and stabilization on site

- 1
2 1 d) A significant change in vital parameters is observed which requires immediate activation of emergency
3
4 2 services
5
6 3 e) Direct hospital admission is considered necessary
7
8 4 f) Ambulatory outpatient visits or tests are planned
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12 6 *Step 2: on site visit by a team of physicians with geriatric expertise*

13
14 7 Visits at the nursing home are performed by two members of the MMU team: an expert hospital physician
15
16 8 chosen on a case-by-case basis among the clinical staff of the Internal Medicine and Critical Subacute Care
17
18 9 Unit, depending on the disease or clinical problem that must be treated, and a specifically trained resident in
19
20 10 Emergency Medicine. The physicians that may be involved in MMU activation include specialists in internal
21
22 11 medicine, clinical ultrasonography, gastroenterology, geriatrics or clinical nutrition.

23
24 12 The team is provided with a car to reach the nursing homes, a portable ultrasound system, and an essential set
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26 13 of drugs and medical devices useful in an emergency setting. The ultrasound system is equipped with three
27
28 14 probes (convex, linear, and phased-array) for performing thoraco-pulmonary, cardiac, vascular, abdominal and
29
30 15 soft tissue ultrasound, when required. Available drugs include those that can be administered intravenously for
31
32 16 treating urgent conditions (e.g. loop diuretics, steroids, fluids, antibiotics). Devices include central and
33
34 17 peripheral venous lines, naso-gastric and rectal tubes and bladder catheters. Blood tests can also be performed.

35
36 18 Table 1 shows possible clinical scenarios which may require MMU team activation, and possible decisions.
37
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42 20 *Step 3: interdisciplinary care planning*

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44 21 Based on the results of the visit and of any performed investigations, the MMU team formulates personalized
45
46 22 advice and referrals, and discusses these with the nursing home physician. If stabilization on site is not deemed
47
48 23 possible, the MMU team plans a direct admission to the Internal Medicine and Critical Subacute Care Unit,
49
50 24 thus avoiding ED access. The planning and the final outcome of the intervention are recorded in the second
51
52 25 part of the form.
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54 26

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56 27 **Feasibility assessment**
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1 A pilot phase of 5 months (December 2018-April 2019) was conducted in two nursing homes in order to look
2 at feasibility of the MMU care Model described above. Before the intervention was introduced, meetings were
3 held with nursing home staff to agree on activation modalities.

4 In this period, 99 phone calls were received, of which 84 required MMU team onsite visits, and 15 were
5 managed with remote consultancy. Of the latter, 3 required direct admission after remote phone consultancy.
6 Only 4 of the 84 patients visited onsite required direct admission. One patient was sent to the ED for massive
7 intestinal bleeding (Figure 2).

8 This phase demonstrated the feasibility of the intervention, and did not highlight any need for modifications.

10 **Evaluation phase**

11 *Aim and objectives*

12 The study aim is to verify the effects of the implementation of the MMU care model tested in the pilot phase.
13 Primary objective is to verify reduction of unplanned hospitalization rates in the nursing homes of the
14 intervention group compared to the nursing homes in the control group. Secondary objectives are to measure
15 the effects of the intervention in terms of mortality, health service use, and costs.

17 *Study Design*

18 This study is a prospective, pragmatic, cluster-multicenter, quasi-experimental study (sequential design with
19 two cohorts), in which usual nursing home care is compared to care provided by applying the MMU model.

20 The cluster design was selected because the intervention is organizational and requires high involvement of all
21 center staff; therefore, randomizing individual clinicians or patients would entail a high risk of contamination
22 bias. A quasi-randomized design was chosen as it prevents the need to discontinue the intervention conducted
23 in two nursing homes which had participated in the pilot phase, and would thus be more acceptable by staff.
24 Furthermore, quasi-experiments do not imply the selection effects and “artificiality” of randomized trials, and
25 are thus more suitable for studies on intervention implementation in real life, enabling a high degree of external
26 validity.²⁷

27 A stepped-wedge design would have been desirable, enabling all participating nursing homes to receive the
28 intervention, but was deemed unfeasible because it entails a larger sample size and study duration; furthermore,

1 the currently available technical and human resources would not be sufficient to sustain MMU intervention
2 delivery in more than two nursing homes at the same time.

3 4 *Study Population*

5 All residents of the participating nursing homes are eligible, regardless of their clinical status. Informed consent
6 will be collected from patients or their proxies/legal representatives, according to the European Union law.
7 Refusal to provide informed consent, either by patients or legal representatives, will imply study exclusion.

8 9 *Usual Care*

10 Patients in the control cohort receive usual care, which means the actions to take are decided by the nursing
11 home staff. Generally, this implies that patients who are clinically unstable, or require urgent instrumental
12 tests, will be sent to the ED.

13 14 *Measures: Baseline variables*

15 Demographic data on gender and age are collected by chart review.

16 17 *Measures: Outcome variables*

18 The primary outcome is hospitalization rate, considering at the numerator all unplanned admissions occurred
19 during a 1-year period, and at the denominator the sum of the person-time of the at risk population (days of
20 stay at the nursing home). For the intervention group, the numerator corresponds to options d) and e) defined
21 in “Step 1: MMU team activation”.

22 The secondary outcomes are the following:

- 23 - Crude all-cause Death Rate (CDR): the number of deaths during 1-year period on person-time of the
24 at risk population
- 25 - Hospital Mortality rate: the frequency of patients who die while in the hospital (death rate/1000)
- 26 - Length of stay (LOS): the duration of a single episode of hospitalization. Inpatient days are calculated
27 by subtracting day of admission from day of discharge.

- 1 1 - Adverse events or complications: frequency of events with novel unexpected worsening of clinical
2
3 2 conditions occurring within 48 hours from MMU team activation, for which hospital access becomes
4
5 3 necessary.
6
7 4 - Costs analysis, comparing the cost differences in the two groups
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10 5 11 12 6 *Data Collection*

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14 7 Patient demographic and clinical characteristics will be collected at baseline from nursing home clinical
15
16 8 records to describe the study population and determine hospital admission rate. For participants in the control
17
18 9 group, only data on age, sex, timing of admission and discharge in nursing home will be collected. For those
19
20 10 in the intervention group, additional data on any MMU activation (reasons, timing, intervention, procedures
21
22 11 and outcomes) will be collected with a specific Case Report Form (CRF).

23
24 12 Participants' files and electronic data will be stored securely at the study site (e.g. locked area, password
25
26 13 protected hard- and software). Data integrity will be scrutinized with several strategies (e.g. valid values, range
27
28 14 checks, consistency checks). Patient data will be only identifiable with the unique participant's number.
29
30 15 Personal information will be collected and saved in a separate file (on a different server) which can only be
31
32 16 accessed by the Principal Investigator (PI). For the primary outcome, information will be obtained using
33
34 17 administrative databases of the hospital and nursing homes. For secondary outcomes the following data sources
35
36 18 will be used: validated regional death registry to determine CDR; electronic discharge summaries to calculate
37
38 19 hospital mortality rate and LOS; electronic ED registry to detect adverse events or complications; hospital
39
40 20 administrative database and CRF for the cost analysis. Residents' identification data will be deleted once the
41
42 21 study is completed, making the dataset anonymous. All study protocol authors will have access to the
43
44 22 anonymous dataset.
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50 24 *Study duration*

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52 25 Overall expected duration is 18 months, with study initiation presumably in November 2019 and completion
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54 26 in April 2021.
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58 28 **Statistical Methodology**

59 60 29 *Sample size calculation*

1 The number of subjects to include was estimated using the findings of Diaz-Gegundez et al, who performed a
2 large quasi-experimental trial.²⁶ Thus, considering 56 cases vs 32 cases per 100 residents, and using a 2-sided,
3 large-samples z-test of the Poisson incidence rate difference at a significance level of 0.05, and with a power
4 of 0.90, overall 338 residents should be enrolled. Since each of the participating nursing homes has between
5 90 and 100 residents, the study appears as feasible.

6 *Statistical analysis plan*

7 Descriptive statistics will be used to summarize patient populations and will be presented as means and
8 standard deviations (SD) when normally distributed, or as medians and interquartile ranges (IQR).

9 For the primary analysis we will use Poisson regression with robust standard errors (SEs) to evaluate relative
10 differences in hospital rates among our two cohorts while adjusting for demographic characteristics.

11 Concerning the secondary outcomes, the following analyses will be performed:

- 12 - Rates will be compared considering the quotient between the intervention and control groups
- 13 - A lognormal model will be used to compare in-hospital LOS.
- 14 - Chi square tests will be conducted for categorical data as adverse events or complications

15 The demographic and clinical variables which influence the outcome with a p value<0.20 in the univariate
16 analysis will be included in the Poisson regression model.

17 Finally, cost analysis will be performed. We will identify the changes in net costs associated with one-year
18 exposure to the intervention, consisting in the induced costs due to incremental resource inputs for carrying
19 out the intervention and hospital health service utilization costs. Staffing costs will be calculated considering
20 the time spent by the professionals involved in the intervention. Non-staff running costs include expenses of
21 MMU staff travelling to and from the nursing home. The health service utilization costs will be identified
22 based on the standard regional tariffs assigned to each admission according to the Diagnosis Related Group
23 (DRG) system. We will use the following equations to summarize the annual net costs associated with the
24 implementation of the intervention. Any costs with negative values mean “savings” and any costs with positive
25 values mean “losses”. Net costs \hat{A} (intervention costs) \pm B (Costs for differences in hospital health service
26 utilization) where: A= intervention: staffing costs+intervention: non- staff costs and B= Costs for differences
27 in inpatient care utilization. Therefore, the net costs arising from one-year implementation of the intervention

1 as compared with the current practice will be obtained, where a negative value of net costs represents “cost-
2 saving” and a positive value represents “not cost-saving”

3 The analyses will be performed using SAS 8.2 (SAS Institute, Cary, NC, USA) and STATA-SE 11 (Stata Corp
4 LP, College Station, TX, USA).

5

6 **ETHICS AND DISSEMINATION**

7 The study will be conducted in compliance with the principles of the revision of the Helsinki Declaration and
8 by current legislation on scientific research. All participants or their legal representatives will sign informed
9 consent form. This study does not entail any experimental pharmacological treatment, or changes in the
10 diagnostic-therapeutic pathway. Eligible patients, or their legal representatives, will be also asked to give
11 written consent to handling of their personal data. If a patient wishes to discontinue his/her participation in the
12 study, it is the responsibility of the investigator to ensure that no further data regarding the person’s health
13 condition shall be collected. All collected data will be used in the final analysis.

14 All data collected, handled and stored for the purpose of this study will be kept confidential at any time and
15 will be securely stored, as required in GCP guidelines and in current privacy legislation.

16

17 **DISCUSSION**

18 The MMU-1 Study will represent one of the first attempts to prevent hospital admissions of nursing home
19 residents by using a multicomponent complex intervention with a strong multidisciplinary approach. Most of
20 previous studies in this field were in fact focused on geriatric routine care, nurse counselling and education,
21 but did not deliver diagnostic and therapeutic interventions at the bedside in case of urgent needs.^{13-19,26} The
22 multidisciplinary skills of MMU-1 staff, that may involve expert physicians with different skills and
23 background depending on the clinical problem of patients, represents a novelty at the current literature state-
24 of-the-art and has a great potential of being successful in preventing hospital admission, considering the high
25 clinical complexity of nursing home residents. The use of bedside ultrasound equipment also represents a high
26 value added to the care of these patients, allowing to reach a high diagnostic accuracy and to perform invasive
27 procedures without moving patients to the hospital.²⁸⁻²⁹ The use of bedside ultrasonography in geriatrics is
28 becoming increasingly popular but is generally unavailable in nursing homes.²⁸⁻²⁹ When integrated with an
29 accurate physical examination, bedside ultrasonography can dramatically improve the diagnostic process,³⁰

1 especially in geriatric multimorbid patients where severity of symptoms, cognitive impairment and mobility-
2 limitations may reduce the accuracy of traditional imaging.²⁸⁻²⁹

3 Finally, the MMU-1 intervention is not fixed into a rigid algorithm, but different kinds of consultancy can be
4 made according to the clinical situation of each patient (Figure 1). This circumstance represents an
5 advancement with respect of other interventions previously described in the literature,¹³ and an effort towards
6 personalization of geriatric care.

7 Some limitations of this study should be considered. First, we acknowledge that the stepped wedge cluster
8 randomized design would represent the best design for testing the effects of a novel care model implemented
9 in multiple nursing homes. However, as described above, this was not feasible due to practical and economic
10 barriers. It is also noteworthy that most of the existing studies included in the Santosaputri review¹³ adopted a
11 quasi-experimental design, because, in research on complex care interventions, methodological soundness
12 must always face practical considerations on feasibility.²⁷

13 In conclusion, if the results of this study suggest benefits for patients and the health care system, future
14 investigations with sounder methodology should be implemented to assess a large-scale application of the
15 proposed care model.

1 1 **Contributors**

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3 2 A.N., B.P., S.L., P.M., E.B., M.F. and T.M. conceptualised the project and designed the intervention. F.D.,
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5 3 A.T., P.S., F.P., B.S. and C.C. provided relevant contributions for study conception and design. E.I. gave
6
7 4 statistical consult. A.N., C.C., F.D. and A.T. drafted the manuscript. All the authors read and approved the
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10 5 final manuscript.

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14 7 **Funding**

15
16 8 This research received no specific grant from any funding agency in the public, commercial or not-for-profit
17
18 9 sectors.

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20 10
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22 11 **Competing interests**

23
24 12 None declared.

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28 14 **Patient consent**

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30 15 Not required.

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34 17 **Ethics approval**

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36
37 18 The study was approved by the competent Ethics Committee (Comitato Etico Area Vasta Emilia Nord),
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39 19 under the ID 846/2019/OSS/AOUPR.

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43 21 **Patient and public involvement**

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45 22 No patient involved.

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TABLE 1

Overview of possible expected clinical situations for which a Multidisciplinary Mobile Unit consultation may be activated, and possible management.

Clinical situation	Clinical question	Mobile Unit Intervention	Disposition
Dyspnea of unknown origin	Pulmonary? Cardiac? Embolism? Other causes?	Chest and Abdomen Ultrasound. Arterial Gas sample, ECG, intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Abdominal pain	Gallbladder stones? Cholecystitis? Renal colic? Diverticular disease? Urinary retention? Faecal impaction? Peritonitis? Ascites? Acute/subacute Hernia?	Abdomen ultrasound, basic blood tests, intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Hematuria	UTI? Catheter dysfunction? Bladder polyps? Stones?	Abdomen ultrasound, Bladder lavage, Catheter (re-)positioning, Intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Psychomotor agitation in previously stable dementia	Inadequate therapy? Emerging internistic problem? Other	CGA, Neurogeriatric visit, exclusion of internistic-emerging problem, ECG, Thoracic&abdominal US	Appropriate diagnosis and treatment on site.
Fever	Origin?	Thoracic&abdominal US, basic blood test	Excluding common differential diagnosis
Absence of peripheral veins for drugs or nutrients infusion	How to find adequate venous access	US guided Central venous catheter or PICC or peripheral access	Securing patient
Monolateral leg edema	DVT? Erysipelas? Trauma?	Venous and soft tissues ultrasound	Appropriate diagnosis and treatment on site.
Terminal illness	Palliation strategy? How to get symptoms relief?	CGA. Multidisciplinary assessment. Positioning of drains (eg abdominal drainage for ascites). Interview with relatives / caregivers and GP for sharing strategies	Appropriate management.
Ultrasound exam in a patient who can be transported with difficulty	GP's question	Abdominal, cardiac, arterial, thyroid, neck ultrasound	Appropriate assessment

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3 ECG = Electrocardiogram; UTI = Urinary Tract Infection; CGA = Comprehensive Geriatric Assessment; US = Ultrasound; PICC = Peripherally-Inserted Central Venous
4 Catheter; DVT = Deep Vein Thrombosis; GP = General Practitioner.
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FIGURE 1

Description of the intervention of MMU Team.

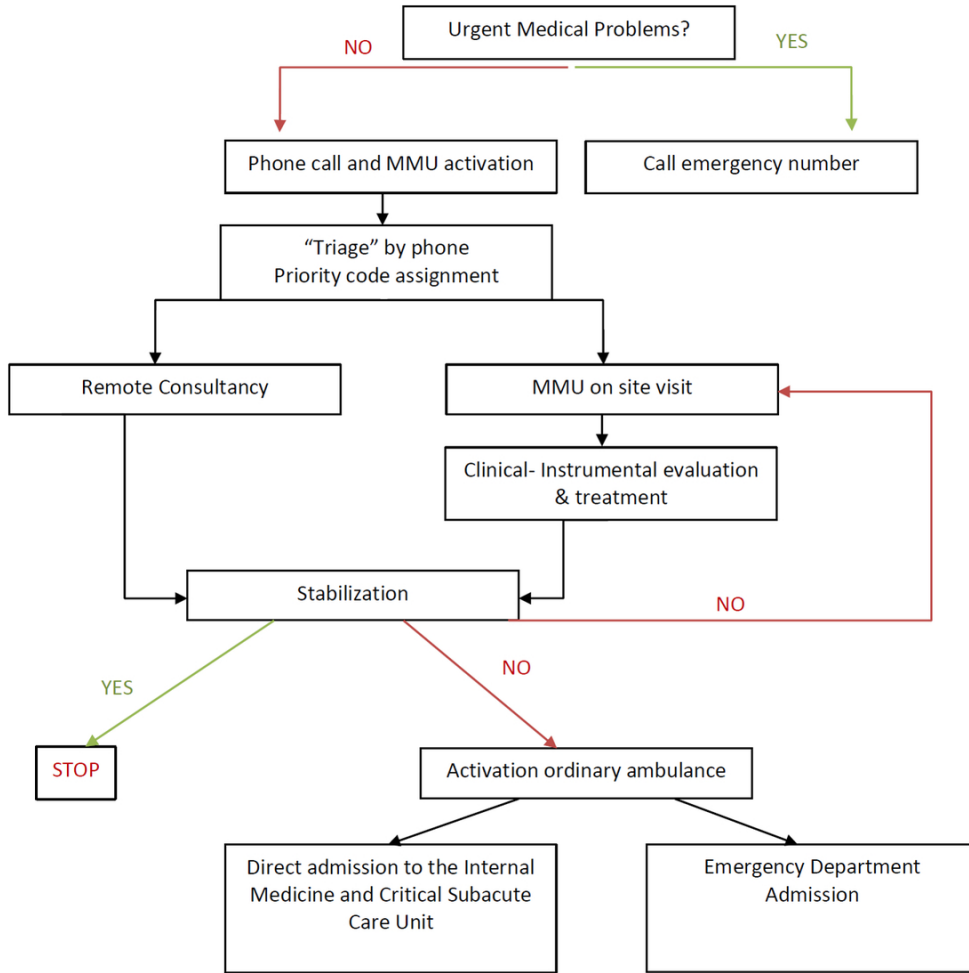
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FIGURE 2

Results of pilot phase.

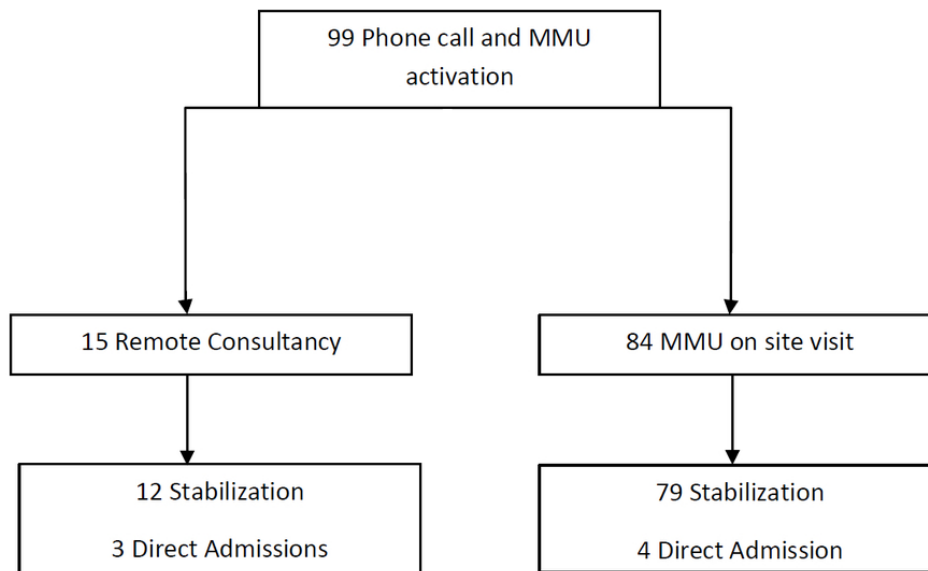
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Description of the intervention of MMU Team

95x95mm (300 x 300 DPI)



Results of pilot phase

78x48mm (300 x 300 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

	Reporting Item	Page Number
Administrative information		
Title	#1 Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

1	Trial registration	#2a	Trial identifier and registry name. If not yet	2, end of abstract
2			registered, name of intended registry	
3				
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6	Trial registration:	#2b	All items from the World Health Organization	2
7	data set		Trial Registration Data Set	
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11	Protocol version	#3	Date and version identifier	Supplemental
12				Material
13				
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16				
17	Funding	#4	Sources and types of financial, material, and	14
18			other support	
19				
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22	Roles and	#5a	Names, affiliations, and roles of protocol	1, 14
23	responsibilities:		contributors	
24	contributorship			
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30	Roles and	#5b	Name and contact information for the trial	N/A (page 14)
31	responsibilities:		sponsor	
32	sponsor contact			
33	information			
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40	Roles and	#5c	Role of study sponsor and funders, if any, in	N/A (page 13)
41	responsibilities:		study design; collection, management, analysis,	
42	sponsor and funder		and interpretation of data; writing of the report;	
43			and the decision to submit the report for	
44			publication, including whether they will have	
45			ultimate authority over any of these activities	
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1	Roles and	#5d	Composition, roles, and responsibilities of the	13
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3	responsibilities:		coordinating centre, steering committee,	
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5	committees		endpoint adjudication committee, data	
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7			management team, and other individuals or	
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9			groups overseeing the trial, if applicable (see	
10				
11			Item 21a for data monitoring committee)	
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15	Introduction			
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18	Background and	#6a	Description of research question and	4-5
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20	rationale		justification for undertaking the trial, including	
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22			summary of relevant studies (published and	
23				
24			unpublished) examining benefits and harms for	
25				
26			each intervention	
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31	Background and	#6b	Explanation for choice of comparators	4-5
32				
33	rationale: choice of			
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35	comparators			
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38	Objectives	#7	Specific objectives or hypotheses	6, 9
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41	Trial design	#8	Description of trial design including type of trial	9-10
42				
43			(eg, parallel group, crossover, factorial, single	
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45			group), allocation ratio, and framework (eg,	
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47			superiority, equivalence, non-inferiority,	
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49			exploratory)	
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54	Methods:			
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56	Participants,			
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1 **interventions, and**

2 **outcomes**

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6 Study setting [#9](#) Description of study settings (eg, community 6
7
8 clinic, academic hospital) and list of countries
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10 where data will be collected. Reference to
11
12 where list of study sites can be obtained
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15 Eligibility criteria [#10](#) Inclusion and exclusion criteria for participants. 10
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17 If applicable, eligibility criteria for study centres
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19 and individuals who will perform the
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21 interventions (eg, surgeons, psychotherapists)
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25 Interventions: [#11a](#) Interventions for each group with sufficient 7-9, 10
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27 description detail to allow replication, including how and
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29 when they will be administered
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33 Interventions: [#11b](#) Criteria for discontinuing or modifying allocated N/A (complex
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35 modifications interventions for a given trial participant (eg, intervention on
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37 drug dose change in response to harms, organization of
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39 participant request, or improving / worsening care)
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42 disease)
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45 Interventions: [#11c](#) Strategies to improve adherence to intervention N/A (the
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47 adherence protocols, and any procedures for monitoring intervention
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49 adherence (eg, drug tablet return; laboratory concerns
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51 tests) organization of care
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1	Interventions:	#11d	Relevant concomitant care and interventions	7-10
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3	concomitant care		that are permitted or prohibited during the trial	
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6	Outcomes	#12	Primary, secondary, and other outcomes,	10
7				
8			including the specific measurement variable	
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11			(eg, systolic blood pressure), analysis metric	
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15			event), method of aggregation (eg, median,	
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17			proportion), and time point for each outcome.	
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19			Explanation of the clinical relevance of chosen	
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21			efficacy and harm outcomes is strongly	
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23			recommended	
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28	Participant timeline	#13	Time schedule of enrolment, interventions	11
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30			(including any run-ins and washouts),	
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32			assessments, and visits for participants. A	
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34			schematic diagram is highly recommended (see	
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36			Figure)	
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40	Sample size	#14	Estimated number of participants needed to	11
41				
42			achieve study objectives and how it was	
43				
44			determined, including clinical and statistical	
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46			assumptions supporting any sample size	
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48			calculations	
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52	Recruitment	#15	Strategies for achieving adequate participant	N/A (all residents in
53				participating nursing
54			enrolment to reach target sample size	homes will be
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eligible for the
study)

Methods:

**Assignment of
interventions (for
controlled trials)**

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A (quasi- experimental study design on organization of care)
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A (quasi- experimental study design on organization of care)
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A (quasi- experimental study design on organization of care)

1	Blinding (masking)	#17a	Who will be blinded after assignment to	N/A (quasi-
2			interventions (eg, trial participants, care	experimental study
3			providers, outcome assessors, data analysts),	design on
4			and how	organization of
5				care)
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13	Blinding (masking):	#17b	If blinded, circumstances under which	N/A (quasi-
14	emergency		unblinding is permissible, and procedure for	experimental study
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16	unblinding		during the trial	organization of
17				care)
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25	Methods: Data			
26	collection,			
27	management, and			
28	analysis			
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35	Data collection plan	#18a	Plans for assessment and collection of	10-11
36			outcome, baseline, and other trial data,	
37			including any related processes to promote	
38			data quality (eg, duplicate measurements,	
39			training of assessors) and a description of study	
40			instruments (eg, questionnaires, laboratory	
41			tests) along with their reliability and validity, if	
42			known. Reference to where data collection	
43			forms can be found, if not in the protocol	
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1 2 3 4 5 6 7 8 9 10 11 12	Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A (quasi-experimental study design on organization of care)
13 14 15 16 17 18 19 20 21 22 23 24 25 26 27	Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11, 13
28 29 30 31 32 33 34 35 36 37	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
38 39 40 41 42	Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
43 44 45 46 47 48 49 50 51 52	Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A due to particular study design

Methods:

Monitoring

1	Data monitoring:	#21a	Composition of data monitoring committee	13
2				
3	formal committee		(DMC); summary of its role and reporting	
4			structure; statement of whether it is	
5			independent from the sponsor and competing	
6			interests; and reference to where further details	
7			about its charter can be found, if not in the	
8			protocol. Alternatively, an explanation of why a	
9			DMC is not needed	
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11	Data monitoring:	#21b	Description of any interim analyses and	13
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13	interim analysis		stopping guidelines, including who will have	
14			access to these interim results and make the	
15			final decision to terminate the trial	
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20	Harms	#22	Plans for collecting, assessing, reporting, and	N/A due to
21			managing solicited and spontaneously reported	particular study
22			adverse events and other unintended effects of	design
23			trial interventions or trial conduct	
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30	Auditing	#23	Frequency and procedures for auditing trial	N/A due to
31			conduct, if any, and whether the process will be	particular study
32			independent from investigators and the sponsor	design
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40	Ethics and			
41	dissemination			
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45	Research ethics	#24	Plans for seeking research ethics committee /	12-13
46				
47	approval		institutional review board (REC / IRB) approval	
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1	Protocol	#25	Plans for communicating important protocol	12-13 +
2				
3	amendments		modifications (eg, changes to eligibility criteria,	supplemental
4			outcomes, analyses) to relevant parties (eg,	material
5			investigators, REC / IRBs, trial participants, trial	
6			registries, journals, regulators)	
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13	Consent or assent	#26a	Who will obtain informed consent or assent	12-13 +
14			from potential trial participants or authorised	supplemental
15			surrogates, and how (see Item 32)	material
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20				
21	Consent or assent:	#26b	Additional consent provisions for collection and	12-13 +
22			use of participant data and biological	supplemental
23	ancillary studies		specimens in ancillary studies, if applicable	material
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29	Confidentiality	#27	How personal information about potential and	12-13 +
30			enrolled participants will be collected, shared,	supplemental
31			and maintained in order to protect	material
32			confidentiality before, during, and after the trial	
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39	Declaration of	#28	Financial and other competing interests for	14
40			principal investigators for the overall trial and	
41	interests		each study site	
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46	Data access	#29	Statement of who will have access to the final	12-13 +
47			trial dataset, and disclosure of contractual	supplemental
48			agreements that limit such access for	material
49			investigators	
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1	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial	N/A due to
2				
3	trial care		care, and for compensation to those who suffer	particular study
4				
5			harm from trial participation	design
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8	Dissemination	#31a	Plans for investigators and sponsor to	13 + supplemental
9				
10	policy: trial results		communicate trial results to participants,	material
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12			healthcare professionals, the public, and other	
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14			relevant groups (eg, via publication, reporting in	
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16			results databases, or other data sharing	
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18			arrangements), including any publication	
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20			restrictions	
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25	Dissemination	#31b	Authorship eligibility guidelines and any	Supplemental
26				
27	policy: authorship		intended use of professional writers	material
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31	Dissemination	#31c	Plans, if any, for granting public access to the	Supplemental
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33	policy: reproducible		full protocol, participant-level dataset, and	material
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35	research		statistical code	
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38	Appendices			
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41	Informed consent	#32	Model consent form and other related	Supplemental
42				
43	materials		documentation given to participants and	material
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45			authorised surrogates	
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49	Biological	#33	Plans for collection, laboratory evaluation, and	N/A due to study
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51	specimens		storage of biological specimens for genetic or	design
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54			molecular analysis in the current trial and for	
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56			future use in ancillary studies, if applicable	
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2 License CC-BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a
3 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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11 **NOTE: The original protocol approved by the competent Ethics Committee (in English language) has**
12 **been uploaded as Supplemental Material.**
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BMJ Open

Implementation of a strategy involving a multidisciplinary mobile unit team to prevent hospital admission in nursing home residents: protocol of a quasi-experimental study (MMU-1 Study)

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1 **1 Implementation of a strategy involving a multidisciplinary mobile unit team to prevent hospital**
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3 **2 admission in nursing home residents: protocol of a quasi-experimental study (MMU-1 Study)**
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6 **3**

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59 **Running Title:** Multidisciplinary mobile unit intervention for nursing homes
60

1 ABSTRACT

2
3 **Introduction-** Nursing home residents represent a particularly vulnerable population experiencing high risk
4
5 of unplanned hospital admissions, but few interventions have proved effective in reducing this risk. The aim
6
7 of this research will be to verify the effects of a hospital-based multidisciplinary mobile unit (MMU) team
8
9 intervention delivering urgent care to nursing home residents directly at their bedside.

10
11 **Methods and analysis-** Four nursing homes based in the Parma province, in Northern Italy, will be involved
12
13 in this prospective, pragmatic, multicenter, 18-month quasi-experimental study (sequential design with two
14
15 cohorts). The residents of two nursing homes will receive the MMU team care intervention. In case of urgent
16
17 care needs, the nursing home physician will contact the hospital physician responsible for the MMU team by
18
19 phone. The case will be triaged as a) manageable by phone advice, b) requiring urgent assessment by the MMU
20
21 team or c) requiring immediate ED referral. MMU team is composed of one senior physician and one
22
23 Emergency-Medicine resident chosen within the staff of Internal Medicine and Critical Subacute Care Unit of
24
25 Parma University-Hospital, usually with different specialty background, and equipped with portable
26
27 ultrasound, set of drugs and devices useful in urgency. The MMU visits patients in nursing homes, with the
28
29 mission to stabilize clinical conditions and avoid hospital admission. Residents of the other two nursing homes
30
31 will receive usual care, i.e. ED referral in every case of urgency. Study endpoints include unplanned hospital
32
33 admissions (primary), crude all-cause mortality, hospital mortality, length of stay and healthcare-related costs
34
35 (secondary).
36
37
38

39 **Ethics and dissemination-** The study protocol was approved by the Ethics Committee of Area Vasta Emilia
40
41 Nord (Emilia-Romagna region). Informed consent will be collected from patients or legal representatives. The
42
43 results will be actively disseminated through peer-reviewed journals and conference presentations, in
44
45 compliance with the Italian law.
46
47

48 **Registration ID-** ClinicalTrials.gov NCT 04085679
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52 **Key words:** multimorbidity; geriatrics; hospitalization; multidisciplinary care; hospital-community
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54 partnership
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1 1 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 2 2 ✓ This study will explore the effectiveness of a complex intervention focused on the avoidance of
- 3 3 hospital admissions for nursing home residents, with a strong hospital-community partnership.
- 4 4 ✓ The study intervention consists in bringing specialist hospital care directly at the bedside of nursing
- 5 5 home residents, an innovative approach not previously described in the scientific literature.
- 6 6 ✓ The intervention has been developed considering the organization of the Italian healthcare system, but
- 7 7 is reproducible and applicable in other settings.
- 8 8 ✓ Due to ethical concerns and the complex nature of the intervention, individual randomization of
- 9 9 participants is not possible.
- 10 10 ✓ The quasi-experimental design of the study allows an optimal compromise between soundness and
- 11 11 feasibility, facilitating the transferability of results into clinical practice.

1 INTRODUCTION

2 The increasing clinical complexity of older medical patients, due to multimorbidity, polypharmacy, frailty,
3 disability and social hardship, is challenging for health care systems.^{1 2} These characteristics are emphasized
4 in nursing home residents, who experience a particularly high risk of Emergency Department (ED) visits and
5 hospitalization (greater than 20% per year).³⁻⁸ In the ED, these patients may experience misdiagnoses and
6 undertreatment, due to their complexity and atypical presentation of acute illness, and contribute to the
7 overcrowding phenomenon.^{4 5 9-11} Once admitted to wards, they are also more likely to have long stays (>2
8 weeks)⁹ and experience hospital-related complications.¹² Additionally, when they are discharged back to
9 nursing homes, they may experience further adverse events related to care transitions.^{6 12}

10 In the light of these considerations, confirmed by large cohort studies conducted in the United States and
11 Canada,^{7 8} a number of approaches have been developed to reduce the risk of hospitalization in nursing home
12 residents. These are summarized in the systematic review by Santosaputri et al,¹³ which includes quantitative
13 comparative studies of all designs aiming to determine the efficacy of interventions provided by geriatric health
14 professionals. Sixteen studies were eligible, of which 6 randomized controlled trials, involving an estimated
15 total of over 7400 patients. The authors of the review categorized 14 intervention programs into three primary
16 approaches (two did not fit in any category):

- 17 - Prevention approach (nine studies): Interventions (such as direct review of patients, telemedicine,
18 comprehensive geriatric assessment) delivered in the nursing home by nurses, physicians, and
19 sometimes allied health personnel to prevent hospitalization of residents
- 20 - Emergency department-based hospital avoidance (three studies): interventions provided by nursing
21 staff (such as wound care or catheter management) targeting nursing home residents during ED visits
- 22 - Post-hospital supported discharge (two studies): Interventions designed to support residents in the care
23 transition from the hospital to nursing home, including geriatrician and nurse review in the facility and
24 standardized rehabilitation programs.

25 Although the majority of the studies reported reductions in hospitalizations, only six, with different designs
26 and interventions, obtained statistically significant findings.¹⁴⁻¹⁹ Two of these studies, with retrospective
27 design, involved delivery of routine care to nursing home residents by hospital-based nursing staff, with the
28 possibility of obtaining support from a geriatrician in case of urgent situations.¹⁴⁻¹⁵ In another prospective
29 quasi-experimental study, a team including a geriatrician and specialized nurses supported the nursing home

1 physician in delivering routine care and in managing urgent clinical situations.¹⁶ The remaining three studies,
2 all with prospective quasi-experimental design, were more focused on selected clinical scenarios, involving
3 advice and education by ED staff to nursing home personnel after ED admission of residents,¹⁷ hospital nurse
4 visits in the nursing home to implement strategies of delirium prevention,¹⁸ and rehabilitation intervention
5 delivered by a geriatric orthopedic team to residents with hip fracture.¹⁹
6 Unfortunately, the quality of evidence was considered low to moderate, therefore further, well-designed studies
7 are needed to identify which interventions are effective in reducing hospitalization in the older residents.¹³ The
8 interventions performed in the existing studies were also mainly focused on routine care, while a prompt and
9 correct management of urgent situations and acute/subacute conditions may be fundamental for avoiding ED
10 admissions in nursing home residents.^{7,20} Namely, interventions delivering urgent care with a multidisciplinary
11 approach, based not only on geriatric expertise but also on the capacity of performing first line diagnostic
12 examinations, such as ultrasonography, and basic invasive procedures, such as central venous line or
13 nasogastric tube insertion, have a great potential of being successful in reducing ED visits, but have not been
14 adequately investigated to date.^{7,20}
15 At our institution, different projects have been carried out for many years to improve care of the elderly,
16 primarily targeting hospital organization, with the main objective to reduce unnecessary, avoidable length of
17 stay (LOS).²¹⁻²³ These efforts benefit in-hospital patients, but are not designed to prevent hospitalizations. In
18 this framework, based on literature evidence, best current knowledge and long-time experience with elderly
19 care developed at our university-hospital, we hypothesize that a complex intervention delivered in nursing
20 homes, where vulnerable high-risk patients live, involving direct patient care by hospital medical staff with
21 multidisciplinary approach grounded on geriatric expertise, may reduce hospitalization of residents.

24 **METHODS AND ANALYSIS**

25 **Study setting**

26 The study is based in the University Hospital of Parma, which has a catchment area of more than 400,000
27 inhabitants, of whom 22.3% is over 65 years old. It provides the only Emergency service of the district, and it
28 ranks fourth in Italy by number of ED visits (yearly average of over 110,000). The average admission rate of
29 the adult ED population is 18%, of which 65% concern people older than 65.

1 In the last two decades, the University Hospital of Parma has implemented several innovative initiatives to
2 manage the hospital flow of frail multimorbid patients and their complex needs. These initiatives included bed
3 management to avoid “bed-blockers”,²¹ physician accountability for the discharge process,²² and creation of a
4 dedicated hospital unit, organized by intensity of care to anticipate the needs of these patients preserving high
5 performance indices.²³ The Multidisciplinary Mobile Unit (MMU) team will be based in this unit, called
6 Internal Medicine and Critical Subacute Care.

7 Nursing homes participating in the study are public facilities of similar size (90-100 residents) which ensure
8 the presence of nursing staff 24 hours a day and of a physician at least 4 hours a day (high-intensity care
9 facilities), in compliance with the care standards set by the Local Health Authority. No staff member is shared
10 among the participating nursing homes. The possible role of distance to the hospital is considered by including
11 in each group one nursing home located next to the hospital and one located at a distance of >5 km.

12 The participating nursing homes are the following CRAs (Casa Residenza Anziani):

- 13 - C.R.A. “I Tigli” Parma (intervention group)
- 14 - C.R.A. “Casa degli Anziani”, Collecchio (intervention group)
- 15 - C.R.A. “Le Tamerici” Parma (control group)
- 16 - C.R.A. “Ines Ubaldi”, Parma (control group)

17 This study follows a multimethod approach, based on the Medical Research Council framework for developing
18 and evaluating complex interventions,²⁴ including the development, feasibility assessment, and evaluation
19 phases.

21 **Development of the intervention**

22 First, the different types of approaches reported in the literature, described above, were considered.¹³ The
23 “prevention approach”, interventions conducted in nursing homes, was chosen as the most suitable strategy to
24 integrate the hospital’s organizational model already in place, as it can target both hospitalization rates and ED
25 overcrowding, allowing to intervene before the person accesses the hospital.

26 Available evidence also prompted us to opt for a multicomponent approach. In fact, the current literature,
27 mainly based on qualitative interviews with nursing home staff members in different countries, suggests that
28 the decision to transfer residents to hospital may be influenced by different factors, such as staffing and skill
29 mix in the nursing homes, treatment options available in the facility, end-of-life decision-making, and

1 1 communication and bureaucratic requirements.²⁵ This multifactorial association means that a multicomponent
2 2 intervention is likely to be more effective than a single-component intervention.²⁶

3 3 Based on the Schippinger¹⁶ and Diaz-Gegundez²⁷ studies, that obtained significant reduction of hospital
4 4 admissions, we created a mobile physician service. Unlike those studies, we did not involve a nurse, because
5 5 the participating facilities have nursing staff available 24 hours a day, and we used medical hospital staff
6 6 because routine clinical management and scheduled follow-up evaluations are already performed by nursing
7 7 home physicians during their office hours.

8 8 Finally, medical hospital staff was preferred to community geriatricians, on the assumption that older patients
9 9 may feel more comfortable being handled by physicians who may have already cared for them at the hospital.
10 10 Moreover, hospital staff enables direct patient referral to the ward. Finally, this allows the use of diagnostic
11 11 technologies available at the hospital, which can be used immediately without the need for hospital admission.

12 12

13 **Description of the intervention**

14 14 The model hinges on the strong collaboration between hospital and nursing home staff to provide residents
15 15 with patient-centered care. It entails a multicomponent intervention which is integrated in standard care and
16 16 comprises three steps: 1) MMU team activation, 2) on site visit by a team of physicians with geriatric expertise,
17 17 3) interdisciplinary care planning (Figure 1).

18 18

19 *Step 1: MMU team activation*

20 20 Patient selection is necessary to ensure that available resources are used for patients who may really benefit.
21 21 To this end, the nursing home physician contacts by phone the “flow manager”, a skilled internist with strong
22 22 clinical expertise, organizational attitude and managerial training, during the 8 a.m.-6 p.m. time frame, Monday
23 23 to Friday. The phone consultation is reported on a form containing the description of the patient’s clinical
24 24 condition and a summary of the conversation. The form also indicates which decision was reached among the
25 25 following six not mutually exclusive options:

- 26 26 a) The patient can be managed by nursing home staff, therapeutic advice is provided by phone
- 27 27 b) Remote reassessment is scheduled after a number of hours agreed upon by the team
- 28 28 c) The MMU team is dispatched for evaluation, treatment and stabilization on site

29 29

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- 1
2 1 d) A significant change in vital parameters is observed which requires immediate activation of emergency
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4 2 services
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6 3 e) Direct hospital admission is considered necessary
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8 4 f) Ambulatory outpatient visits or tests are planned
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12 6 *Step 2: on site visit by a team of physicians with geriatric expertise*

13
14 7 Visits at the nursing home are performed by two members of the MMU team: an expert hospital physician
15
16 8 chosen on a case-by-case basis among the clinical staff of the Internal Medicine and Critical Subacute Care
17
18 9 Unit, depending on the disease or clinical problem that must be treated, and a specifically trained resident in
19
20 10 Emergency Medicine. The physicians that may be involved in MMU activation include specialists in internal
21
22 11 medicine, clinical ultrasonography, gastroenterology, geriatrics or clinical nutrition.

23
24 12 The team is provided with a car to reach the nursing homes, a portable ultrasound system, and an essential set
25
26 13 of drugs and medical devices useful in an emergency setting. The ultrasound system is equipped with three
27
28 14 probes (convex, linear, and phased-array) for performing thoraco-pulmonary, cardiac, vascular, abdominal and
29
30 15 soft tissue ultrasound, when required. Available drugs include those that can be administered intravenously for
31
32 16 treating urgent conditions (e.g. loop diuretics, steroids, fluids, antibiotics). Devices include central and
33
34 17 peripheral venous lines, naso-gastric and rectal tubes and bladder catheters. Blood tests can also be performed.
35
36 18 Table 1 shows possible clinical scenarios which may require MMU team activation, and possible decisions.
37
38 19

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40
41 20 *Step 3: interdisciplinary care planning*

42
43 21 Based on the results of the visit and of any performed investigations, the MMU team formulates personalized
44
45 22 advice and referrals, and discusses these with the nursing home physician. If stabilization on site is not deemed
46
47 23 possible, the MMU team plans a direct admission to the Internal Medicine and Critical Subacute Care Unit,
48
49 24 thus avoiding ED access. The planning and the final outcome of the intervention are recorded in the second
50
51 25 part of the form.
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56 27 **Feasibility assessment**

57
58 28 A pilot phase of 5 months (December 2018-April 2019) was conducted in the two nursing homes participating
59
60 29 to the study as intervention group, in order to look at feasibility of the MMU care Model described above.

1 1 Before the intervention was introduced, meetings were held with nursing home staff to agree on activation
2 2 modalities.

3 3 In this period, 99 phone calls were received, of which 84 required MMU team onsite visits, and 15 were
4 4 managed with remote consultancy. Of the latter, 3 required direct admission after remote phone consultancy.

5 5 Only 4 of the 84 patients visited onsite required direct admission. One patient was sent to the ED for massive
6 6 intestinal bleeding (Figure 2).

7 7 This phase demonstrated the feasibility of the intervention, and did not highlight any need for modifications.

8 8

9 **Evaluation phase (current study)**

10 *Aim and objectives*

11 11 The study aim is to verify the effects of the implementation of the MMU care model tested in the pilot phase.

12 12 Primary objective is to verify reduction of unplanned hospitalization rates in the nursing homes of the
13 13 intervention group compared to the nursing homes in the control group. Secondary objectives are to measure
14 14 the effects of the intervention in terms of crude all-cause mortality, hospital mortality, length of stay and
15 15 healthcare-related costs.

16 16

17 *Study Design*

18 18 This study is a prospective, pragmatic, cluster-multicenter, quasi-experimental study (sequential design with
19 19 two cohorts), in which usual nursing home care is compared to care provided by applying the MMU model.

20 20 The cluster design was selected because the intervention is organizational and requires high involvement of all
21 21 center staff; therefore, randomizing individual clinicians or patients would entail a high risk of contamination
22 22 bias. A quasi-randomized design was chosen as it prevents the need to discontinue the intervention conducted
23 23 in two nursing homes which had participated in the pilot phase, and would thus be more acceptable by staff.

24 24 Furthermore, quasi-experiments do not imply the selection effects and “artificiality” of randomized trials, and
25 25 are thus more suitable for studies on intervention implementation in real life, enabling a high degree of external
26 26 validity.²⁸

27 27

28 *Study Population*

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30 30

1 All residents staying in the participating nursing homes at the moment of study initiation or admitted afterwards
2 are eligible for inclusion, regardless of their clinical status. Informed consent will be collected from patients
3 or their proxies/legal representatives, according to the European Union law. Refusal to provide informed
4 consent, either by patients or legal representatives, will imply study exclusion.

6 *Usual Care*

7 Patients in the control cohort receive usual care, which means the actions to take are decided by the nursing
8 home staff. Generally, this implies that patients who are clinically unstable, or require urgent instrumental
9 tests, will be sent to the ED.

11 *Measures: Baseline variables*

12 Demographic data on gender and age are collected by chart review.

14 *Measures: Outcome variables*

15 The primary outcome is hospitalization rate, considering at the numerator all unplanned admissions occurred
16 during a 1-year period, and at the denominator the sum of the person-time of the at risk population (days of
17 stay at the nursing home). For the intervention group, the numerator corresponds to options d) and e) defined
18 in “Step 1: MMU team activation” (activation of Emergency services and direct hospital admission).

19 The secondary outcomes are the following:

- 20 - Crude all-cause Death Rate (CDR): the number of deaths during 1-year period on person-time of the
21 at risk population
- 22 - Hospital Mortality rate: the frequency of patients who die while in the hospital (death rate/1000)
- 23 - Length of stay (LOS): the duration of a single episode of hospitalization. Inpatient days are calculated
24 by subtracting day of admission from day of discharge.
- 25 - Adverse events or complications: frequency of events with novel unexpected worsening of clinical
26 conditions, defined as alterations of vital signs, occurring within 48 hours from MMU team activation,
27 for which hospital access becomes necessary.
- 28 - Costs analysis, comparing the cost differences in the two groups

1 *Data Collection*

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3 2 Patient demographic and clinical characteristics will be collected at baseline from nursing home clinical
4
5 3 records to describe the study population and determine hospital admission rate. For participants in the control
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7 4 group, only data on age, sex, timing of admission and discharge in nursing home will be collected. For those
8
9 5 in the intervention group, additional data on any MMU activation (reasons, timing, intervention, procedures
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11 6 and outcomes) will be collected with a specific Case Report Form (CRF).
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13 7 Participants' files and electronic data will be stored securely at the study site (e.g. locked area, password
14
15 8 protected hard- and software). Data integrity will be scrutinized with several strategies (e.g. valid values, range
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17 9 checks, consistency checks). Patient data will be only identifiable with the unique participant's number.
18
19 10 Personal information will be collected and saved in a separate file (on a different server) which can only be
20
21 11 accessed by the Principal Investigator (PI). For the primary outcome, information will be obtained using
22
23 12 administrative databases of the hospital and nursing homes. For secondary outcomes the following data sources
24
25 13 will be used: validated regional death registry to determine CDR; electronic discharge summaries to calculate
26
27 14 hospital mortality rate and LOS; electronic ED registry to detect adverse events or complications; hospital
28
29 15 administrative database and CRF for the cost analysis. Residents' identification data will be deleted once the
30
31 16 study is completed, making the dataset anonymous. All study protocol authors will have access to the
32
33 17 anonymous dataset.
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39 *Study duration*

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41 20 Overall expected duration is 18 months, with study initiation presumably in January 2020 and completion in
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43 21 June 2021.
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48 **Statistical Methodology**

49 *Sample size calculation*

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51 25 The number of subjects to include was estimated using the findings of Diaz-Gegundez et al, who performed a
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53 26 large quasi-experimental trial.²⁷ Thus, considering 56 cases vs 32 cases per 100 residents, and using a 2-sided,
54
55 27 large-samples z-test of the Poisson incidence rate difference at a significance level of 0.05, and with a power
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57 28 of 0.90, overall 338 residents should be enrolled. Since each of the participating nursing homes has between
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59 29 90 and 100 residents, the study appears as feasible.
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Statistical analysis plan

Descriptive statistics will be used to summarize patient populations and will be presented as means and standard deviations (SD) when normally distributed, or as medians and interquartile ranges (IQR).

For the primary analysis we will use Poisson regression with robust standard errors (SEs) to evaluate relative differences in hospital rates among our two cohorts while adjusting for demographic characteristics.

Concerning the secondary outcomes, the following analyses will be performed:

- Rates will be compared considering the quotient between the intervention and control groups
- A lognormal model will be used to compare in-hospital LOS.
- Chi square tests will be conducted for categorical data as adverse events or complications

The demographic and clinical variables which influence the outcome with a p value < 0.20 in the univariate analysis will be included in the Poisson regression model.

Finally, cost analysis will be performed. We will identify the changes in net costs associated with one-year exposure to the intervention, consisting in the induced costs due to incremental resource inputs for carrying out the intervention and hospital health service utilization costs. Staffing costs will be calculated considering the time spent by the professionals involved in the intervention. Non-staff running costs include expenses of MMU staff travelling to and from the nursing home. The health service utilization costs will be identified based on the standard regional tariffs assigned to each admission according to the Diagnosis Related Group (DRG) system. We will use the following equations to summarize the annual net costs associated with the implementation of the intervention. Any costs with negative values mean “savings” and any costs with positive values mean “losses”. Net costs = A (intervention costs) ± B (Costs for differences in hospital health service utilization) where: A = intervention: staffing costs + intervention: non-staff costs and B = Costs for differences in inpatient care utilization. Therefore, the net costs arising from one-year implementation of the intervention as compared with the current practice will be obtained, where a negative value of net costs represents “cost-saving” and a positive value represents “not cost-saving”

The analyses will be performed using SAS 8.2 (SAS Institute, Cary, NC, USA) and STATA-SE 11 (Stata Corp LP, College Station, TX, USA).

Patient and public involvement

1 1 No patient involved.

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3 2

4 3 **ETHICS AND DISSEMINATION**

5 4 The study will be conducted in compliance with the principles of the revision of the Helsinki Declaration and
6 5 by current legislation on scientific research. All participants or their legal representatives will sign informed
7 6 consent form. This study does not entail any experimental pharmacological treatment, or changes in the
8 7 diagnostic-therapeutic pathway. Eligible patients, or their legal representatives, will be also asked to give
9 8 written consent to handling of their personal data. If a patient wishes to discontinue his/her participation in the
10 9 study, it is the responsibility of the investigator to ensure that no further data regarding the person's health
11 10 condition shall be collected. All collected data will be used in the final analysis.

12 11 All data collected, handled and stored for the purpose of this study will be kept confidential at any time and
13 12 will be securely stored, as required in GCP guidelines and in current privacy legislation.

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16 15 **DISCUSSION**

17 16 The MMU-1 Study will represent one of the first attempts to prevent hospital admissions of nursing home
18 17 residents by using a multicomponent complex intervention with a strong multidisciplinary approach. Most of
19 18 previous studies in this field were in fact focused on geriatric routine care, nurse counselling and education,
20 19 but did not deliver diagnostic and therapeutic interventions at the bedside in case of urgent needs.^{13-19,27} The
21 20 multidisciplinary skills of MMU-1 staff, that may involve expert physicians with different skills and
22 21 background depending on the clinical problem of patients, represents a novelty at the current literature state-
23 22 of-the-art and has a great potential of being successful in preventing hospital admission, considering the high
24 23 clinical complexity of nursing home residents. The use of bedside ultrasound equipment also represents a high
25 24 value added to the care of these patients, allowing to reach a high diagnostic accuracy and to perform invasive
26 25 procedures without moving patients to the hospital.²⁹⁻³⁰ The use of bedside ultrasonography in geriatrics is
27 26 becoming increasingly popular but is generally unavailable in nursing homes.²⁹⁻³⁰ When integrated with an
28 27 accurate physical examination, bedside ultrasonography can dramatically improve the diagnostic process,³¹
29 28 especially in geriatric multimorbid patients where severity of symptoms, cognitive impairment and mobility-
30 29 limitations may reduce the accuracy of traditional imaging.²⁹⁻³⁰

1 Finally, the MMU-1 intervention is not fixed into a rigid algorithm, but different kinds of consultancy can be
2 made according to the clinical situation of each patient (Figure 1). This circumstance represents an
3 advancement with respect of other interventions previously described in the literature,¹³ and an effort towards
4 personalization of geriatric care. Even in the two studies by Schippinger¹⁶ and Diaz-Gegundez²⁷ reporting a
5 significant reduction of hospital admissions, the intervention was rather fixed, centered exclusively on
6 comprehensive geriatric assessment and lacked technological support such as bedside ultrasound.

7 Some limitations of this study should be considered. First, we acknowledge that the stepped wedge cluster
8 randomized design would represent the best design for testing the effects of a novel care model implemented
9 in multiple nursing homes. However, this was not feasible due to practical and economic barriers. In fact, it
10 entails a larger sample size and study duration, and the currently available technical and human resources
11 would not be sufficient to sustain MMU intervention delivery in more than two nursing homes at the same
12 time. It is also noteworthy that most of the existing studies included in the Santosaputri review¹³ adopted a
13 quasi-experimental design, because, in research on complex care interventions, methodological soundness
14 must always face practical considerations on feasibility.²⁸

15 In conclusion, if the results of this study suggest benefits for patients and the health care system, future
16 investigations with sounder methodology should be implemented to assess a large-scale application of the
17 proposed care model.

1 1 **Contributors**

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3 2 A.N., B.P., S.L., P.M., E.B., M.F. and T.M. conceptualised the project and designed the intervention. F.D.,
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5 3 A.T., P.S., F.P., B.S. and C.C. provided relevant contributions for study conception and design. E.I. gave
6
7 4 statistical consult. A.N., C.C., F.D. and A.T. drafted the manuscript. All the authors read and approved the
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10 5 final manuscript.

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15
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17
18 9 sectors.

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22 11 **Competing interests**

23
24 12 None declared.

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28 14 **Patient consent**

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30 15 Not required.

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34 17 **Ethics approval**

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37 18 The study was approved by the competent Ethics Committee (Comitato Etico Area Vasta Emilia Nord,
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39 19 Emilia-Romagna region), under the ID 846/2019/OSS/AOUPR.

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TABLE 1

Overview of possible expected clinical situations for which a Multidisciplinary Mobile Unit consultation may be activated, and possible management.

Clinical situation	Clinical question	Mobile Unit Intervention	Disposition
Dyspnea of unknown origin	Pulmonary? Cardiac? Embolism? Other causes?	Chest and Abdomen Ultrasound. Arterial Gas sample, ECG, intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Abdominal pain	Gallbladder stones? Cholecystitis? Renal colic? Diverticular disease? Urinary retention? Faecal impaction? Peritonitis? Ascites? Acute/subacute Hernia?	Abdomen ultrasound, basic blood tests, intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Hematuria	UTI? Catheter dysfunction? Bladder polyps? Stones?	Abdomen ultrasound, Bladder lavage, Catheter (re-)positioning, Intravenous antibiotic administration	Appropriate diagnosis and treatment on site. Immediate or scheduled admission whenever appropriate
Psychomotor agitation in previously stable dementia	Inadequate therapy? Emerging internistic problem? Other	CGA, Neurogeriatric visit, exclusion of internistic-emerging problem, ECG, Thoracic&abdominal US	Appropriate diagnosis and treatment on site.
Fever	Origin?	Thoracic&abdominal US, basic blood test	Excluding common differential diagnosis
Absence of peripheral veins for drugs or nutrients infusion	How to find adequate venous access	US guided Central venous catheter or PICC or peripheral access	Securing patient
Monolateral leg edema	DVT? Erysipelas? Trauma?	Venous and soft tissues ultrasound	Appropriate diagnosis and treatment on site.
Terminal illness	Palliation strategy? How to get symptoms relief?	CGA. Multidisciplinary assessment. Positioning of drains (eg abdominal drainage for ascites). Interview with relatives / caregivers and GP for sharing strategies	Appropriate management.
Ultrasound exam in a patient who can be transported with difficulty	GP's question	Abdominal, cardiac, arterial, thyroid, neck ultrasound	Appropriate assessment

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3 ECG = Electrocardiogram; UTI = Urinary Tract Infection; CGA = Comprehensive Geriatric Assessment; US = Ultrasound; PICC = Peripherally-Inserted Central Venous
4 Catheter; DVT = Deep Vein Thrombosis; GP = General Practitioner.
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FIGURE 1

Description of the intervention of MMU Team.

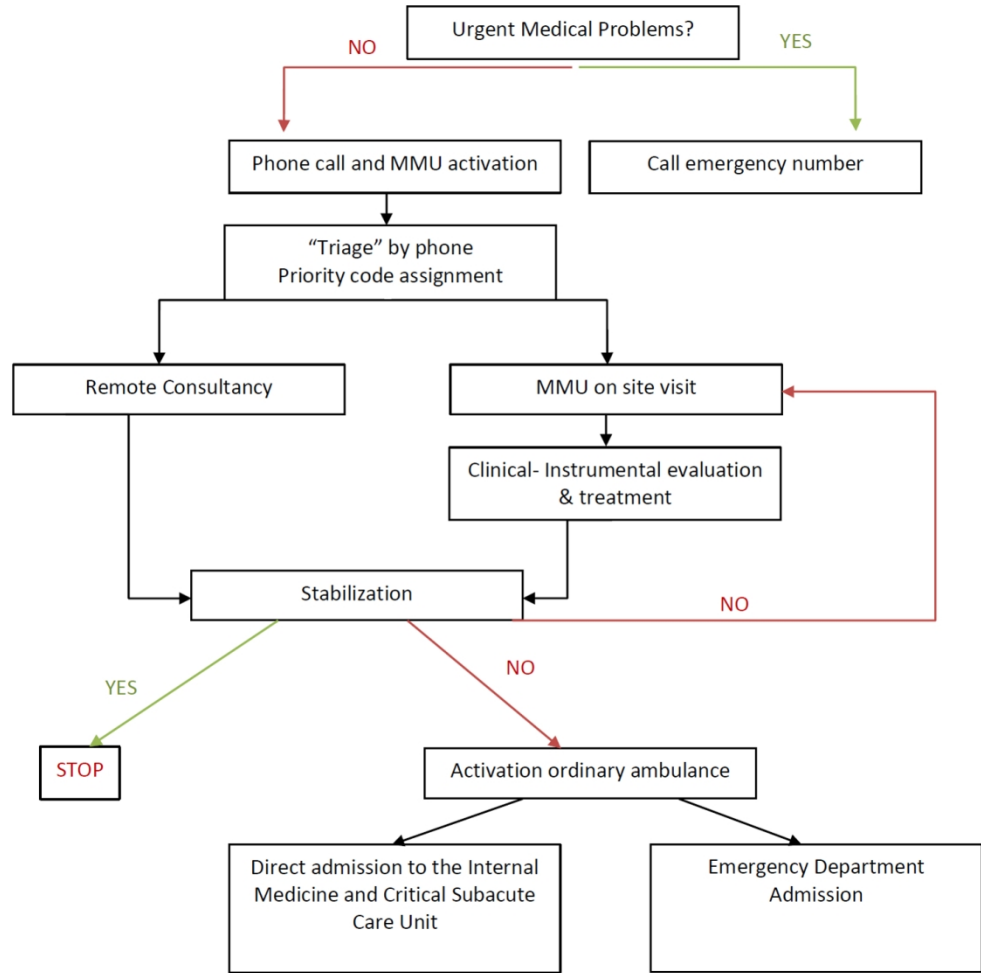
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FIGURE 2

Results of pilot phase.

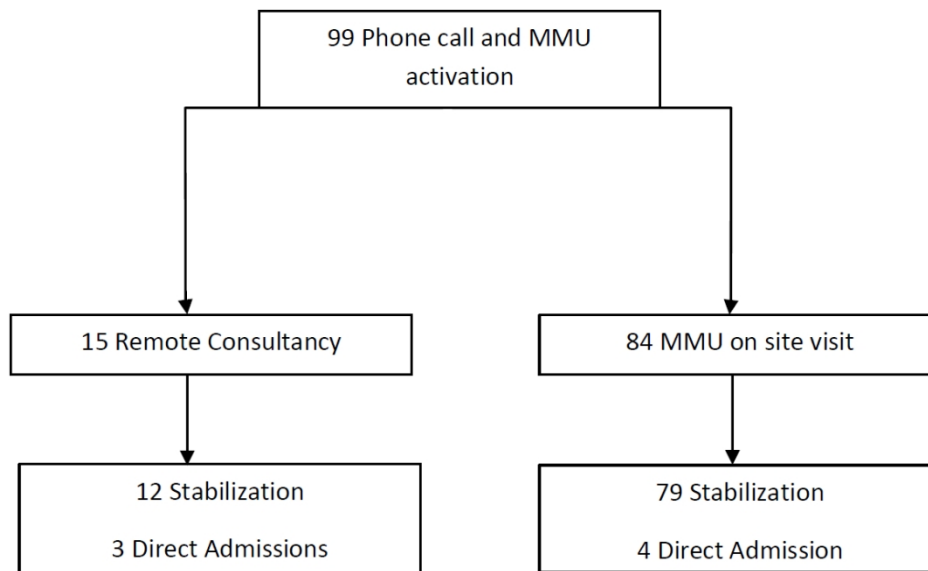
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Description of the intervention of MMU Team

95x95mm (400 x 400 DPI)



Results of pilot phase

78x48mm (400 x 400 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

	Reporting Item	Page Number
Administrative information		
Title	#1 Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

1	Trial registration	#2a	Trial identifier and registry name. If not yet	2, end of abstract
2			registered, name of intended registry	
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6	Trial registration:	#2b	All items from the World Health Organization	2
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17	Funding	#4	Sources and types of financial, material, and	14
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23	Roles and	#5a	Names, affiliations, and roles of protocol	1, 14
24				
25	responsibilities:		contributors	
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27	contributorship			
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30	Roles and	#5b	Name and contact information for the trial	N/A (page 14)
31				
32	responsibilities:		sponsor	
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34	sponsor contact			
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37	information			
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40	Roles and	#5c	Role of study sponsor and funders, if any, in	N/A (page 13)
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42	responsibilities:		study design; collection, management, analysis,	
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44	sponsor and funder		and interpretation of data; writing of the report;	
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1	Roles and	#5d	Composition, roles, and responsibilities of the	13
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11			Item 21a for data monitoring committee)	
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15	Introduction			
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18	Background and	#6a	Description of research question and	4-5
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20	rationale		justification for undertaking the trial, including	
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22			summary of relevant studies (published and	
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24			unpublished) examining benefits and harms for	
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31	Background and	#6b	Explanation for choice of comparators	4-5
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33	rationale: choice of			
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38	Objectives	#7	Specific objectives or hypotheses	6, 9
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41	Trial design	#8	Description of trial design including type of trial	9-10
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43			(eg, parallel group, crossover, factorial, single	
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45			group), allocation ratio, and framework (eg,	
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Methods:

Participants,

1 interventions, and

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3 outcomes

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6 Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
7 8 9 10 11 12 13 14			
15 Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
16 17 18 19 20 21 22 23 24			
25 Interventions: 26 description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9, 10
27 28 29 30 31 32			
33 Interventions: 34 modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A (complex intervention on organization of care)
35 36 37 38 39 40 41 42 43 44			
45 Interventions: 46 adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A (the intervention concerns organization of care in nursing homes)
47 48 49 50 51 52 53 54 55 56 57 58 59 60			

1	Interventions:	#11d	Relevant concomitant care and interventions	7-10
2				
3	concomitant care		that are permitted or prohibited during the trial	
4				
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6	Outcomes	#12	Primary, secondary, and other outcomes,	10
7				
8			including the specific measurement variable	
9				
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11			(eg, systolic blood pressure), analysis metric	
12				
13			(eg, change from baseline, final value, time to	
14				
15			event), method of aggregation (eg, median,	
16				
17			proportion), and time point for each outcome.	
18				
19			Explanation of the clinical relevance of chosen	
20				
21			efficacy and harm outcomes is strongly	
22				
23			recommended	
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28	Participant timeline	#13	Time schedule of enrolment, interventions	11
29				
30			(including any run-ins and washouts),	
31				
32			assessments, and visits for participants. A	
33				
34			schematic diagram is highly recommended (see	
35				
36			Figure)	
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40	Sample size	#14	Estimated number of participants needed to	11
41				
42			achieve study objectives and how it was	
43				
44			determined, including clinical and statistical	
45				
46			assumptions supporting any sample size	
47				
48			calculations	
49				
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52	Recruitment	#15	Strategies for achieving adequate participant	N/A (all residents in
53				participating nursing
54			enrolment to reach target sample size	homes will be
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eligible for the
study)

Methods:

**Assignment of
interventions (for
controlled trials)**

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A (quasi- experimental study design on organization of care)
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A (quasi- experimental study design on organization of care)
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A (quasi- experimental study design on organization of care)

1	Blinding (masking)	#17a	Who will be blinded after assignment to	N/A (quasi-
2			interventions (eg, trial participants, care	experimental study
3			providers, outcome assessors, data analysts),	design on
4			and how	organization of
5				care)
6				
7				
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12				
13	Blinding (masking):	#17b	If blinded, circumstances under which	N/A (quasi-
14	emergency		unblinding is permissible, and procedure for	experimental study
15			revealing a participant's allocated intervention	design on
16	unblinding		during the trial	organization of
17				care)
18				
19				
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25	Methods: Data			
26	collection,			
27	management, and			
28	analysis			
29				
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35	Data collection plan	#18a	Plans for assessment and collection of	10-11
36			outcome, baseline, and other trial data,	
37			including any related processes to promote	
38			data quality (eg, duplicate measurements,	
39			training of assessors) and a description of study	
40			instruments (eg, questionnaires, laboratory	
41			tests) along with their reliability and validity, if	
42			known. Reference to where data collection	
43			forms can be found, if not in the protocol	
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1 2 3 4 5 6 7 8 9 10 11 12	Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A (quasi-experimental study design on organization of care)
13 14 15 16 17 18 19 20 21 22 23 24 25 26 27	Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11, 13
28 29 30 31 32 33 34 35 36 37	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
38 39 40 41 42	Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
43 44 45 46 47 48 49 50 51 52	Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A due to particular study design

Methods:

Monitoring

1	Data monitoring:	#21a	Composition of data monitoring committee	13
2				
3	formal committee		(DMC); summary of its role and reporting	
4			structure; statement of whether it is	
5			independent from the sponsor and competing	
6			interests; and reference to where further details	
7			about its charter can be found, if not in the	
8			protocol. Alternatively, an explanation of why a	
9			DMC is not needed	
10				
11	Data monitoring:	#21b	Description of any interim analyses and	13
12				
13	interim analysis		stopping guidelines, including who will have	
14			access to these interim results and make the	
15			final decision to terminate the trial	
16				
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20	Harms	#22	Plans for collecting, assessing, reporting, and	N/A due to
21			managing solicited and spontaneously reported	particular study
22			adverse events and other unintended effects of	design
23			trial interventions or trial conduct	
24				
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30	Auditing	#23	Frequency and procedures for auditing trial	N/A due to
31			conduct, if any, and whether the process will be	particular study
32			independent from investigators and the sponsor	design
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40	Ethics and			
41	dissemination			
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45	Research ethics	#24	Plans for seeking research ethics committee /	12-13
46				
47	approval		institutional review board (REC / IRB) approval	
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1	Protocol	#25	Plans for communicating important protocol	12-13 +
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3	amendments		modifications (eg, changes to eligibility criteria,	supplemental
4			outcomes, analyses) to relevant parties (eg,	material
5			investigators, REC / IRBs, trial participants, trial	
6			registries, journals, regulators)	
7				
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13	Consent or assent	#26a	Who will obtain informed consent or assent	12-13 +
14			from potential trial participants or authorised	supplemental
15			surrogates, and how (see Item 32)	material
16				
17				
18				
19				
20				
21	Consent or assent:	#26b	Additional consent provisions for collection and	12-13 +
22	ancillary studies		use of participant data and biological	supplemental
23			specimens in ancillary studies, if applicable	material
24				
25				
26				
27				
28	Confidentiality	#27	How personal information about potential and	12-13 +
29			enrolled participants will be collected, shared,	supplemental
30			and maintained in order to protect	material
31			confidentiality before, during, and after the trial	
32				
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38	Declaration of	#28	Financial and other competing interests for	14
39	interests		principal investigators for the overall trial and	
40			each study site	
41				
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46	Data access	#29	Statement of who will have access to the final	12-13 +
47			trial dataset, and disclosure of contractual	supplemental
48			agreements that limit such access for	material
49			investigators	
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1	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial	N/A due to
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3	trial care		care, and for compensation to those who suffer	particular study
4				
5			harm from trial participation	design
6				
7				
8	Dissemination	#31a	Plans for investigators and sponsor to	13 + supplemental
9				
10	policy: trial results		communicate trial results to participants,	material
11				
12			healthcare professionals, the public, and other	
13				
14			relevant groups (eg, via publication, reporting in	
15				
16			results databases, or other data sharing	
17				
18			arrangements), including any publication	
19				
20			restrictions	
21				
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23				
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25	Dissemination	#31b	Authorship eligibility guidelines and any	Supplemental
26				
27	policy: authorship		intended use of professional writers	material
28				
29				
30				
31	Dissemination	#31c	Plans, if any, for granting public access to the	Supplemental
32				
33	policy: reproducible		full protocol, participant-level dataset, and	material
34				
35	research		statistical code	
36				
37				
38	Appendices			
39				
40				
41	Informed consent	#32	Model consent form and other related	Supplemental
42				
43	materials		documentation given to participants and	material
44				
45			authorised surrogates	
46				
47				
48				
49	Biological	#33	Plans for collection, laboratory evaluation, and	N/A due to study
50				
51	specimens		storage of biological specimens for genetic or	design
52				
53				
54			molecular analysis in the current trial and for	
55				
56			future use in ancillary studies, if applicable	
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2 License CC-BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a
3 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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11 **NOTE: The original protocol approved by the competent Ethics Committee (in English language) has**
12 **been uploaded as Supplemental Material.**
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