Author’s response to reviews

Title: Feasibility of using risk prompts to prevent falls, dehydration and pulmonary aspiration in nursing homes: a clinical study protocol

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Author’s response to reviews:

Carmel Hughes, MPharm PhD
Associate Editor
Pilot and Feasibility Studies Journal

Dear Prof. Carmel Hughes,

We hereby resubmit our revised manuscript entitled “Feasibility of using risk prompts to prevent falls, dehydration and pulmonary aspiration in nursing homes: a clinical study protocol” (PAFS-D-17-00088) and we thank the opportunity to submit a revised version for publication in Pilot and Feasibility Studies journal.

We appreciate the time and efforts by the associate editor and referees in reviewing this manuscript. We have revised the manuscript in accordance with the comments and suggestions raised. We enclose below a point-by-point response to the issues raised by the reviewers specifying the changes made to the revised version of the manuscript.
We hope the revised version will now be suitable for publication at the Pilot and Feasibility Studies journal.

Yours sincerely,

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Reviewer #2: Review of manuscript PAFS-D-17-00088 "Feasibility of using risk prompts to prevent falls, dehydration, and pulmonary aspiration in nursing homes: a clinical study protocol"

Thank you for asking me to review this manuscript. In this study protocol, the authors outline the background and methods for the above study, which aims to evaluate the feasibility of using a set of written signs (prompts) to caution against falls, dehydration and pulmonary aspiration risks in a nursing home population. This manuscript could be of interest to the readership of the Journal, although it does require significant work to address my concerns, and editorial input is needed to improve the level of English, should it be accepted for publication. The authors do not appear to have adhered to the SPIRIT checklist as a guide for reporting (and there is no SPIRIT figure included); use of this would help to improve the quality of the manuscript and reporting procedure. I have provided detailed comments forthwith with reference to the page/line number:
Title

1. The title is OK and is reflective of the study

Abstract (most of these comments will also be applicable to the main body of the manuscript)

2. Page 2, Line 4: Health professionals - what professional groups are you referring to here?

Response: We are grateful to the reviewer for his guidance in improving the manuscript, in concrete for this observation. We were referring to all health professionals working in nursing homes (physicians, nurses, rehabilitation team, psychologist, social workers, dieticians and medical assistants). To improve communication between the different groups of health professionals may decrease the number of adverse events in institutionalized patients. To be clear to the reader to who are we referring the sentence has been changed (abstract, page 2, lines 4-7):

“It is believed that improving communication among health professionals in nursing homes (physicians, nurses, rehabilitation team, psychologist, social workers, dieticians and medical assistants) decreases the number of adverse events in institutionalized patients.”

3. Page 2, Line 10: Abbreviation of CNS - what does this mean?

Response: We thank the reviewer for this observation. The abbreviation has been spelled out in the abstract (page 2, line 10) and in the “Methods” section (page 4, line 6) of the manuscript.
4. Page 2, Line 10/11: What are the inclusion criteria?

Response: We thank the reviewer for this pertinent observation. The sentences of “Methods and analysis” abstract section, referring to patients’ selection have been reformulated in order to be clear what will be the inclusion criteria of the study (page 2, lines 11-13):

“All patients from Campus Neurológico Sénior (CNS) nursing home, with risk of falling and/or dysphagia and/or dehydration will be invited to participate in the study.”

5. Page 2, Line 13: What do 'events' refer to?

Response: We thank the reviewer for this pertinent observation. Events refer to the incidents of falls, dehydration and pulmonary aspiration suffered by patients. In order to be easy reading, we have changed the sentence in the abstract (page 2, lines 14-17) and in “Methods” section (page 8, lines 16-19):

“Study duration will be a minimum of three months per participant, including daily record of falls, dehydration and pulmonary aspiration events and monthly interview assessments, conducted by a member of the research team.”

“This will contain information about the study duration and will present a summary of the number of participants in the study (number of patients recruited and number of drop-outs) and of the falls, dehydration and pulmonary aspiration events recorded in that month.”
6. Page 2, Line 14: Interview assessments: with whom are these going to be conducted?

Response: We thank the reviewer for this important comment. A nurse, member of the research team, will conduct the interviews. We added this information to the manuscript in the abstract (page 2, lines 14-17) and in “Methods” section (page 8, lines 3-5):

“Study duration will be a minimum of three months per participant, including daily record of falls, dehydration and pulmonary aspiration events and monthly interview assessments, conducted by a member of the research team.”

“At the end of each month, patients will undergo an interview performed by a nurse (member of the research team), and a self-completed questionnaire will be handed to health care professionals.”

7. Page 2, Line 14: 'Data of events' - again, what do the authors mean by this exactly?

Response: We thank the reviewer for this comment. In line with the suggestions made by the reviewer in point 5, we reformulated the sentence to be more explicit to what are we referring to (page 2, lines 14-18):

“Study duration will be a minimum of three months per participant, including daily record of falls, dehydration and pulmonary aspiration events and monthly interview assessments, conducted by a member of the research team. Data of the occurred events will be compared with historical data extracted retrospectively from medical and nursing charts.”
8. Page 2, Line 18: Provide ethics reference please

Response: We thank the reviewer for this important suggestion. The ethics reference has been added to the abstract (page 2, lines 19-21):

“This study has been approved by the Ethics Committees of the Medical Academic Center of Lisbon, Faculty of Medicine, University of Lisbon (Ref. 176/15).”

9. Page 2, Line 18: Is this written informed consent? Please stipulate

Response: We thank the reviewer for this pertinent comment. We rewrote the sentence in the abstract (page 2, lines 21-22), specifying the type of inform consent that it will be asked:

“All participants will give their written informed consent before entering the study.”

10. Page 2, Line 19: The authors state this study is unique - why so?

Response: We thank the reviewer for this comment. There are not much studies addressing risk prevention in nursing homes. In concrete, to our knowledge, there are no previous similar studies evaluating a system, based on health professionals' communication/ access to information, to prevent the three major risks for nursing home residents. To clarify this issue, the abstract has been changed (page 2, lines 23-24):

“This study is unique in evaluating the feasibility of a communication system to prevent the three major risks in nursing home.”
11. Page 3, Lines 5 and 7: what do the authors mean by 'health care facilities'?

Response: We thank the reviewer for this question. Health care facilities are any standalone building where health care is provided, with 24-hours inpatient services. Once this study protocol will be conducted in a nursing home, in order to be clearer we opted for replacing the term “health care facilities” for “nursing homes”, and to use it in a standardize manner in all manuscript.

12. Page 3, Line 8: Please provide clarification on the multidisciplinary team members to whom you are referring in this context

Response: We thank the reviewer for this observation. Given the heterogeneity of diagnoses, functional status and individual characteristics, a multidisciplinary team including physicians, nurses, professionals from rehabilitation team, psychologists, social workers and medical assistants is needed to ensure the best disease management and to improve patients’ care. The introduction has been changed to be clearer which professionals should be included in multidisciplinary teams of nursing homes (page 3, line 20-24):

“To provide high quality care and prevent these risks, nursing home multidisciplinary team members (i.e. physicians, nurses, professionals from rehabilitation team, psychologists, social workers and medical assistants) need to work as a coordinated team, to have an effective system of communication and to comprehend the needs of residents.”

13. The authors then go on to write about the use of written risk prompts, however I was still unsure as to who initiate these prompts usually, e.g. is it management? And who are they aimed at - are they for the patients, staff or both? Who is privy to the information on them? What do they look like? I know that further information is later provided in the methods section but the reader does need to know some of this early on in the introduction so that the rest of the paper makes sense! How exactly are they meant to work? If better context was provided in relation to
these 'prompts' I think I would have understood the protocol and it's aims/purpose better. More
detail and background needs to be provided here.

Response: We thank the reviewer for his questions and suggestion. In order to be more
understandable to the reader the system that will be tested, the end of the introduction has been
reformulated and some details about risk prompts has been added (page 3, lines 25-31):

“The used of risk prompt displays by nursing homes patients, may improve the access to
information and communication between health professionals, which may reduce the number of
falls, dehydration and pulmonary aspiration events. In patients’ admission, the nursing team
would be responsible for screening for falls, dehydration and pulmonary aspiration risks and for
suggesting the corresponding risk prompt displays. The local multidisciplinary team would
validate nurse team suggestion, before patients start using the risk displays in their daily routine
in the nursing home.”

14. Only one reference appears to be provided (number 8; Colon-Emeric et al., 2013) for most of
the introductory section. Is this the only work that has been done in the area? What exactly is
known already? Again, I think this could be better expanded upon to provide a richer and more
detailed context and background for the reader.

Response: We thank the reviewer for this comment. There is not much evidence in risk
prevention in nursing homes and the available is specially focused in falls prevention. However,
according to reviewer’s suggestion we restructured and rewritten the “Introduction” section in
order to enrich the background to the reader (page 3 and 4):

“Due to demographic ageing and increased life expectancy, an increasing number of elderly
people have to spend the end of their life in institutional settings. [1]

Nursing homes provide 24h-nursing care to residents with the heterogeneity of diagnoses,
different degrees of functional status and complex care needs. (3) Falls, pulmonary aspiration,
and dehydration are a particular problem in nursing homes and a major contribution to the
deterioration of independence and quality-of-life of residents. [2–7]
The incidence of falls and fall-related injuries among persons living in institutions has been reported in numerous epidemiologic studies, being a major external cause of death in nursing homes. [8–10] Choking and aspiration pneumonia are also frequent. Choking is the most common external cause of death in residents younger than 65. Aspiration pneumonia is particularly difficult to diagnose, since the moment of aspiration is usually not observed. [8,11] Dehydration, due to the poor fluid intake or pathologic loss of body fluids, was considered to be present in 0.8% to 1.4% of nursing home residents. It is associated with frailty, poor cognition, falls, delirium, disability, and mortality and it’s a major cause of decreased attention and fluctuating mental status, the hallmarks of delirium, in the nursing home. [12]

To provide high quality care and prevent these risks, nursing home multidisciplinary team members (i.e. physicians, nurses, professionals from rehabilitation team, psychologists, social workers and medical assistants) need to work as a coordinated team, to have an effective system of communication and access to information, and to comprehend the residents’ needs. [13,14]

The use of risk prompt displays by nursing homes patients, may improve the access to information and communication between health professionals, which may reduce the number of falls, dehydration and pulmonary aspiration events. In patients’ admission, the nursing team would be responsible for screening for falls, dehydration and pulmonary aspiration risks and for suggesting the corresponding risk prompt displays. The local multidisciplinary team would validate nurse team suggestion, before patients start using the risk displays in their daily routine in the nursing home.

The aim of this study is to develop and evaluate the feasibility of a set of risk prompt display to communicate falls, dehydration and pulmonary aspiration risks and to reflect on tailored interventions to manage these events in nursing homes. In order to that a national, single-centre, feasibility study will be conducted. The duration of the study for each participant will be a minimum of three months.”

Methods/Design

15. Page 3, Line 30: National - where?
Response: We thank the reviewer for this relevant observation. This information has been added to “Methods” section (page 4, lines 9-12):

“Participants will be recruited from Campus Neurológico Sénior (CNS), a neurological nursing home, located in Torres Vedras, Portugal, which counts with an outpatient clinic and a residential unit for short or long-term admissions of neurologic patients or individuals aged over 65 years.”

16. Page 3, Line 31: ’3’ should be written as ‘three’. All numbers under ten should be written out in full.

Response: We thank the reviewer for this comment. According to it the number has been written out in full (page 4, lines 4-5):

“The duration of the study for each participant will be a minimum of three months.”

17. The aim and primary/secondary objectives are then listed. These should really be at the end of the introductory section.

Response: We thank the reviewer for this comment. According to Spirit guidelines, specific objectives or hypotheses should be mentioned in introduction and the outcomes in methods section. To avoid misleading the readers, we now present the aim of the study in the end of the introduction (page 4, lines 1-5) and the outcomes in “Methods section”, before “Statistical analysis” section (from page 8, line 31 to page 9, line 7):

“The aim of this study is to develop and evaluate the feasibility of a set of risk prompt display to communicate falls, dehydration and pulmonary aspiration, risks and to reflect on tailored interventions to manage these events in nursing homes. In order to that a national, single-centre,
feasibility study will be conducted. The duration of the study for each participant will be a minimum of three months.”

“Primary outcome

To evaluate the feasibility of risk prompt displays designed to communicate risks.

Secondary outcome:

The secondary outcome will be to evaluate:

- Patients’ and health professionals’ satisfaction;

- The efficacy of risk prompt displays in reducing the number of falls, pulmonary aspiration and dehydration events;

- The type and frequency of adverse events that arise from using the risk prompt displays (for example: physical discomfort, social discomfort, skin irritability, stress or anxiety).”

18. I think there needs to be some re-organisation of headings/material presented in the methods section. The authors could provide some further information with regard to setting of the study, explaining about where the study is set and how representative this is of long-term care facilities in Portugal

Response: We thank the reviewer for this pertinent suggestion. The “Methods” section has been restructured according to PRISMA guidelines. Also, according to reviewer’s suggestion a subsection named “Study setting” has been added (page 4, 8-15):
“Study setting

Participants will be recruited from Campus Neurológico Sénior (CNS), a neurological nursing home, located in Torres Vedras, Portugal, which counts with an outpatient clinic and a residential unit for short or long-term admissions of neurologic patients or individuals aged over 65 years. CNS places its focus on a comprehensive care to patients, implemented by a multidisciplinary healthcare team that includes physicians, nurses, a rehabilitation team, dieticians, psychologists and medical assistants.”

19. Page 3, Line 17: I think this heading would sound better if termed 'Sampling' rather than 'patient population'

Response: We thank the reviewer for this suggestion and we agree with it. According to the reviewer’s suggestion in the last point the methods sections has been reorganized and has been used the structure and terminology of PRISMA guidelines. This section in now termed “Eligibility criteria” (page 4, lines 17-29):

“Eligibility criteria

All patients from CNS residential unit who fulfil the following inclusion criteria will be invited to participate:

• Men or women residing at CNS nursing home for long-term care;

• Risk of falling and/or dysphagia and/or dehydration defined by brief screening assessment;

• Willing to participate in the study;

• Willing to provide written informed consent;

• Willing to comply with the monthly required interviews;
Exclusion criteria include the presence of significant active psychiatric problems (e.g.: hallucinations, confusion, psychosis) that, according to the clinical judgement of the CNS multidisciplinary team, could be aggravated with the use of risk reminders.”

20. Page 3, Line 18: Again, CNS…??? What does this stand for, what does it mean? Why is only one nursing home being used? How representative is this of nursing home care/older nursing home population? Again this feeds into my earlier comment around needing to provide context for the study setting

Response: We thank the reviewer for this comment. As mentioned in point 3 the abbreviation of Campus Neurológico Sénior (CNS) has been spelled out in the manuscript. Being the population of CNS representative in ages, heterogeneity of symptoms and variability of functional status of the institutionalized people in Portugal, and being this a first exploratory study, we assume that running it in only one nursing will not compromise the ability to conclude on the primary outcome on feasibility. However, this issue is referred, in “Discussion” section, as a possible limitation of the study (page 10, lines 24-28):

“This study will only be conducted in one nursing home, which could be a limitation. However, CNS population is representative in ages, heterogeneity of diagnosis and symptoms of nursing homes reality. Being this is a protocol for a first exploratory study, we anticipate that running the study in just one nursing home will not compromise the capability to conclude on patients’ adherence.”

21. Page 3, Line 19: Add 'listed below/listed forthwith' after …'if they fulfil inclusion criteria'

Response: We thank the reviewer for this suggestion. According to it, the sentence has been changed (page 4, line 18-25):

“All patients from CNS residential unit who fulfil the following inclusion criteria will be invited to participate:
• Men or women residing at CNS nursing home for long-term care;

• Risk of falling and/or dysphagia and/or dehydration defined by brief screening assessment;

• Willing to participate in the study;

• Willing to provide written informed consent;

• Willing to comply with the monthly required interviews.”

22. Page 3, Line 20: What exactly is meant by the ‘multidisciplinary team’? Again, you need to be explicit for the international readership as to the multidisciplinary team members from the nursing home to whom this intervention is aimed

Response: We thank the reviewer for this comment and we agree with it. This issue has been addressed in general in the introduction (see point 12 or manuscript page 3, lines 20-24). We have also added this information in “study setting” subsection to clarify which health professionals are part of it (page 4, lines 12-15):

“CNS places its focus on a comprehensive care to patients, implemented by a multidisciplinary healthcare team that includes physicians, nurses, a rehabilitation team, dieticians, psychologists and medical assistants.”
23. Page 3, Line 23: Is there any stipulation as to how long patients need to have been resident in the nursing home, in order to participate in the study?

Response: We thank the reviewer for this important comment. The duration of the study for each participant will be a minimum of three months. Because of that one of our inclusion criteria is “Men or women residing at CNS nursing home for long-term care”. Also, patients’ adherence and frequency of events would be calculated as relative frequency (number of times and reasons to take off the risk prompts or number of events / number of days of hospitalization), not as absolute frequency.

24. Page 3, Lines 24/25: What is this brief screening assessment? Is there a reference that can be provided here?

Response: We thank the reviewer for his questions. We use the term “brief assessment” in opposition to a detailed examination of all factors that can contribute to risk of falling, pulmonary aspiration and/or dehydration. To clarify this topic, we reformulated the sentence, indicating which clinical scales compose the brief assessment (page 6, lines 21-23):

“In addition, a brief clinical assessment of risk of falling, pulmonary aspiration and dehydration, including the clinical scales listed below, will be performed.”

25. Page 3, Line 26: Reword to 'Willing to participate in the study'

26. Page 3, Line 27: 'Willing to provide written informed consent'

Response: We thank the reviewer for his suggestions. According to it, the sentences have been changed (page 4, lines 21 and 22).
27. Page 3, Lines 29/30: This point has already been stated above - and I wonder if this is an inclusion criterion? It is more about how patients have been identified/screened

Response: We thank the reviewer for his suggestion and we agree with it. This point has been moved from the inclusion criteria to the “Screening” subsection (page 5, lines 23-25):

“Patients’ risks definition and inclusion in the study will require a clinical assessment to investigate the current presence of one or more risks, knowledge of the patient's history and validation by the CNS multidisciplinary team during a meeting.”

28. Page 4, Line 10: What is this clinical screening assessment?

Response: We thank the reviewer for his question. With clinical screening assessment we are referring to a series of clinical test made in order to evaluate participants’ eligibility to be enrolled in the study. To be easier to understand to what are we referring to, the sentence has been changed (page 5, lines 23-25):

“Patients’ risks definition and inclusion in the study will require a clinical assessment to investigate the current presence of one or more risks, knowledge of the patient's history and validation by the CNS multidisciplinary team during a meeting.”

29. Page 4, Line 11: The authors describe 'significant active' psychiatric problems - how have they qualified these terms? How long does the problem have to have been active for?

Response: We thank the reviewer for his question. The evaluation of the impact of psychiatric problems will be discussed and decided based on the clinical judgement of the CNS multidisciplinary team. We have changed the sentence to clarify this issue (page 4, line 27-29):
“Exclusion criteria include the presence of significant active psychiatric problems (e.g.: hallucinations, confusion, psychosis) that, according to the clinical judgement of the CNS multidisciplinary team, could be aggravated with the use of risk reminders.”

30. Page 4, Line 15: I think there could be better wording for this subheading 'study supplies'

Response: We thank the reviewer for this suggestion. The subheading “study supplies” has been changed to “study materials” (page 4, line 29).

31. Figures 1 and 2 are very helpful to the reader to visualise what these prompts actually look like. However, I have no idea if these are standard/have they been used before, or have these been invented.designed by the research team?

Response: We thank the reviewer for these comments and questions. The CNS risk prompt display study group has designed the risk prompts. It aims to be implement, after validated, in CNS everyday routine. We added this information to the manuscript (page 5, lines 1-7):

“Created by the CNS risk prompt display study group, the risk reminders are intended to be used by residents, since admission, in CNS everyday routine (after validated with the present feasibility study). They include standardized:

- Small, lightweight rubber coloured bracelets, for patients’ use (in the wrist, visible), with phrases related to the different risks: “prevent rather than fall”, “contain to protect”, “drink to hydrate” and “avoid choking”.

- Small and coloured signposts next to put next to patients’ bed headboard.”
32. Can you explain a bit more about how each of these prompts are actually utilised? For example, who wears the bracelets? What do they actually say? What do the signs actually say/show?

Response: We thank the reviewer for these comments and questions. We address this issue in the previous point (point 31).

33. Page 4, Line 24: Again, who are these healthcare professionals exactly? Who are these teaching sessions aimed at? Are they run as multidisciplinary sessions? I think these paragraph needs more detail added - what form does the 60 min session take? Deal with the detail sequentially.

Response: We thank the reviewer for these comments and questions. In order to be more understandable to the reader, this subsection has been restructured and some details were added (page 5, lines 11-18):

“One member of the research team, to train and familiarize the CNS multidisciplinary team with the use of sign displays and the corresponding intervention procedures, will hold an initial multidisciplinary teaching session. The training is expected to last 60 minutes, and to be a theory/practical session. It will include the explanation of what constitutes a fall, pulmonary aspiration and dehydration, and specific instructions on which procedures to undertake at each risk situation. Additionally, the researcher will exemplify the procedure practically and any queries from professionals will be explained.”

34. Page 5: I wondered if this paragraph would be better termed as 'recruitment'?

Response: We thank the reviewer for this suggestion. In order to better reflect what will be address and according with the reviewer suggestion, we renamed the subsection as “Recruitment and Intervention”. The following paragraph from “Eligibility criteria” section has been moved to “Screening” subsection (from page 5, lines 26 to page 6, line 4):
“For the purpose of participant recruitment, a fall is defined as a sudden, unexpected event that results in coming to rest unintentionally on the ground or at some other lower level. [15,16] A near fall is defined as an involuntary or uncontrolled descent not ending on the ground or at some other lower level. [17] Given our interest in the phenomena and not the cause, all falls, either resulting from environmental hazards or overwhelming external force, disease-related symptoms and/or attributable to acute medical events such as syncope and seizures, will be considered.

A dysphagia or pulmonary aspiration event will be defined as inefficient or unsafe transfer of food, liquid or saliva from the mouth into the stomach. [18]

Dehydration will be defined by the loss of body water, with or without salt, at a rate greater than the body can replace it.”

35. Page 5, Line 1: Insert 'the aforementioned' before 'inclusion criteria'

Response: We thank the reviewer for this suggestion. According to it the sentence (page 5, lines 21-22) has been reformulated:

“All patients will be invited to participate if they fulfil the previous mentioned inclusion criteria.”

36. Page 5, Line 3: Again, to whom are you referring when mentioning the multidisciplinary team?

Response: We thank the reviewer for this comment. This issue has been address in point 22.

37. Page 5, Line 5: Is there a contingency plan in place if a resident does not have any legal guardians to provide consent on their behalf? Will they then be excluded from the study?
Response: We thank the reviewer for this comment. When a patient is admitted to a nursing home, is part of the current practice, to determine who is the legal guardian. This is done by asking directly to the family and, when needed, with the support of the institution's lawyer. Therefore, we do not expect to have to deal with this problem.

38. Page 5, Line 7: Didn't understand the term 'voluntariness'

Response: We thank the reviewer for this observation. With “voluntariness” we are referring to the patient will to participate (in opposition of being coerced). To clarify this issue the term “voluntariness” has been changed in the manuscript to “willingness” (page 6, line 8-11):

“Informed consent containing comprehensive information about objectives, duration, procedures, willingness and possible risks to study participation, will be obtained from patients before any study-related proceedings.”

39. How long do potential participants have to consider the study information before they have to decide whether or not they will take part?

Response: We thank the reviewer for this question. Patients need time to consider if they want or not to take part in the study and should not be rushed into decisions. They will be encouraged to take time to think and to clarify any doubts they may have before signing informed consent. Once they are CNS residents with daily contact with members of the research team, a standardized period for decision has not been established. This information has been added to the manuscript (page 6, lines 11-13):

“Patients will be encouraged to take time to think, to clarify any doubts they may have before signing informed consent and, when they feel ready, to communicate the decision to one of the members of the research team.”
40. I then wonder if the sub-heading 'screening' is more appropriate to be inserted before the paragraph starting 'Demographic data, clinical manifestations and disease management…'?

Response: We thank the reviewer for this suggestion. The “Procedures” section has been restructured. The referred paragraph was removed from “Screening” subsection and a new subsection “Baseline” has been created and included: (from page 5, line 20 to page 6, line 23):

“2) Screening

All patients will be invited to participate if they fulfil the previous mentioned inclusion criteria. The nursing team from CNS nursing home will propose patients for recruitment. Patients’ risks definition and inclusion in the study will require a clinical assessment to investigate the current presence of one or more risks, knowledge of the patient's history and validation by the CNS multidisciplinary team during a meeting.

For the purpose of participant recruitment, a fall is defined as a sudden, unexpected event that results in coming to rest unintentionally on the ground or at some other lower level. [15,16] A near fall is defined as an involuntary or uncontrolled descent not ending on the ground or at some other lower level. [17] Given our interest in the phenomena and not the cause, all falls, either resulting from environmental hazards or overwhelming external force, disease-related symptoms and/or attributable to acute medical events such as syncope and seizures, will be considered.

A dysphagia or pulmonary aspiration event will be defined as inefficient or unsafe transfer of food, liquid or saliva from the mouth into the stomach. [18]

Dehydration will be defined by the loss of body water, with or without salt, at a rate greater than the body can replace it. [19]

At the end of screening and risk assessment, the corresponding risk messages will be given to patient by the investigator.
In case of incapacity of patients to give informed consent, legal guardians will then be asked for consent and authorization of a screening visit. Informed consent containing comprehensive information about objectives, duration, procedures, willingness and possible risks to study participation, will be obtained from patients before any study-related proceedings. Patients will be encouraged to take time to think, to clarify any doubts they may have before signing informed consent and, when they feel ready, to communicate the decision to one of the members of the research team. During the screening visit, an explanation of the objectives and compliance needed for the study will be given to the participants and caregivers and all questions will be considered and answered.

3) Baseline assessment

Demographic data, clinical manifestations and disease management, co-morbidities and past medical conditions will be obtained using a structured questionnaire. In addition, a brief clinical assessment of risk of falling, pulmonary aspiration and dehydration, including the clinical scales listed below, will be performed.”

41. Page 5, Line 24: Change 'cognition impairment' to 'cognitive impairment'

Response: We thank the reviewer for this comment. The term has been corrected in the manuscript (page 6, line 26).

42. TUG test can also be used as an indicator of frailty in older people

Response: We thank the reviewer for this comment and we agree with it. Time Up and Go (TUG) test is not only used to assess risk of fall, but also to assess frailty and functional mobility (mobility, balance, walking ability). This information and the respective reference has been added to the paragraph of TUG description (page 7, lines 1-10):
“Timed Up and Go Test (TUG) [21–23]

The TUG is a quick capacity measure to assess frailty, functional mobility and a good predictor of an individual’s ability to independently walk outside safely. It requires that the participant get up from a standard chair, walk 3m at a comfortable and safe speed and then turn walk to back to sit in the chair. The TUG is recommended in the latest physiotherapy guidelines and by the International Parkinson and Movement Disorder Society (MDS) Rating Scales Committee as an instrument to assess posture, gait, and balance in Parkinson’s disease. It is also recommended as a tool to identify frailty and risk of fall in the older population (cut-off score indicating risk of falls > 13.5 seconds).”

43. More detail needs to be provided about some of the scale mentioned, particularly in terms of total mark/scoring procedures, e.g. MMSE has no information on scoring/scoring categories/severity of cognitive impairment as denoted by scoring

Response: We thank the reviewer for this observation. We added some more information to MMSE, TUG tests and Morse Falls Scale (from page 6, line 25 to page 7, line 18):

“The Mini Mental State Examination (MMSE) [20]

The MMSE is a brief 30-item questionnaire that is used to quantitatively assess cognition. The MMSE test consists of 11 simple questions grouped into 7 cognitive domains: the time and place of the test, repetition of three words, attention and calculation, recall of three words, language use and visual construction. It can be used to screen for cognitive impairment (cut-off scores: none: 24-30; mild: 18-24; and severe: 0-17), to estimate the severity of cognitive impairment at a given point in time, to follow the course of cognitive changes over time, and to document individual’s response to treatment.

Timed Up and Go Test (TUG) [21–23]

The TUG is a quick capacity measure to assess frailty, functional mobility and a good predictor of an individual’s ability to independently walk outside safely. It requires that the participant get up from a standard chair, walk 3m at a comfortable and safe speed and then turn walk to back to
sit in the chair. The TUG is recommended in the latest physiotherapy guidelines and by the International Parkinson and Movement Disorder Society (MDS) Rating Scales Committee as an instrument to assess posture, gait, and balance in Parkinson’s disease. It is also recommended as a tool to identify frailty and risk of fall in the older population (cut-off score indicating risk of falls > 13.5 seconds).

Morse Falls Scale [24]

The Morse Falls Scale assesses the risk of falling for hospital inpatients or those in long-term care. In particular it evaluates: falls history, the presence of comorbidities, the use of walking aids, mental status and whether or not patients are receiving intravenous therapy. Each criterion evaluated receives a score ranging from zero to 30 points, totalizing a risk score, which is classified as follows: low risk, from 0 - 24; mean risk, 25-44; and high risk, ≥45.”

44. Page 6, Line 2: Is there a reference for these latest physiotherapy guidelines for PD?

Response: We thank the reviewer for this question. The references for each tool appear next to the name of the scale. In concrete the reference for physiotherapy guidelines for PD appears in page 6, line 31 (reference number 16).

45. Some of these screening tools are self-report measures - what happens if the resident is unable to provide a self-report? Is a proxy report used from staff member/family member? Or is the resident excluded from the study?

Response: We thank the reviewer for this question. If the patient is unable to provide a self-report, once the questionnaire refers to observable external aspects, it will be asked to a CNS nurse, familiar with the patient's history, to fulfil the questionnaire. This information has been added to the Swallowing Disturbance Questionnaire description (page 7, lines 25-26):
“If the patient is unable to respond, it will be asked to a CNS nurses familiar with the patient's history, to fulfil this questionnaire.”

46. Under 'diary record' please provide detail as to who has created these documents

Response: We thank the reviewer for this observation. The “diary records” has been specifically created for this study by the CNS risk prompt display study group (already previously mentioned). To be more specific, the term “CNS working staff” has been changed to “CNS risk prompt display study group” (page 8, line 2-4):

“In the end of each nursing shift all events of falls, near falls, dehydration and pulmonary aspiration will be recorded in documents, specifically created for this purpose, by the CNS risk prompt display study group.”

47. Page 7: Again, as regards information gathered during the monthly interview - what will you do if information is missing - will you go to a proxy? Have these interviews been piloted?

Response: We thank the reviewer the observation. The questions included in monthly interviews refer to satisfaction and usability questions, whereby the answer is personal. Demented patients are a large part of nursing home population and are unable to respond to this type of questions. In order to avoid exclude these patients and threaten the external validity of the study, we opted for assuming this limitation. The register of adverse events and the perspective of health professionals, cannot replace the missing data, but will probably minimize its impact. This information has been added to the manuscript (page 8, lines 13-15):

“In order to avoid excluding demented patients, in case of the patients being unable to answer to the questions, will register only the occurrence of adverse events and will be recorded the reason for not performing the interview.”
48. Have researchers received training in administering the screening tests listed?

Response: We thank the reviewer for this question. The researchers will not receive a specific training for this study since they are already familiarized with the screening tests through the collaboration in previous clinical studies and because these tests are included in CNS assessment protocol applied to all patients in the admission.

49. Page 6, Line 26/27: Provide reference for SPSS in brackets

Response: We thank the reviewer comment. We will use SPSS (Chicago, IL) as one of the statistical analysis tools recommended by SPIRIT guidelines. The reference has been added to the manuscript.

50. Page 6, Line 27: What kinds of descriptive statistics will be used?

Response: We thank the reviewer for his question. Data will be analysed using means, medians and relative frequencies. This information has been added to “Statistical Analysis” section (page 9, line 11-13):

“The statistical analysis will be performed using SPSS® version 21.0; SPSS Inc. Chicago, IL. [28] Data will be described using descriptive statistics, in concrete means, medians and relative frequencies (i.e. outcome per number of days of hospitalization).”

51. Page 6, Line 28/29: Can you provide more detail as to how this figure of 20 patients/residents was decided upon? If from previous experience/studies then provide references for these
Response: We thank the reviewer for this question. Since this is an exploratory study, with no previous studies, based on the study of Tickle-Degnen, 2013, we proposed 20 participants as sufficient to conclude on patients’ adherence. The reference has been added to the manuscript.

52. Page 6, Line 31: This needs to be reworded - doesn't make sense: 'performing a very weigh study…'

Response: We thank the reviewer comment. The sentence has been changed (page 9, line 15-17):

“This is a compromise between the capability to respond to a specific question and a realistic perspective of recruitment capacity using just one nursing home.”

53. Page 6, Line 38: 'as our primary outcome we will measure patients' adherence' - this doesn't make sense to me; adherence to what exactly?

Response: We thank the reviewer comment. Being this a feasibility study, our primary outcome will be patients’ adherence to the risk prompts, which will be measured through the number of times and reasons to take off the risk prompts or refusal to use prompts during the period of the study and/or withdrawing from the study. To be more easy reader the sentence has been changed (page 9, line 18-20):

“As our primary outcome, we will measure patients’ adherence to the risk prompts through the number of times and reasons to take off the risk prompts or refusal to use prompts during the period of the study and/or withdrawing from the study.”
54. Page 7: In relation to data record - how/where will patient data be stored?

Response: We thank the reviewer for this question. The study documents will be stored in CNS in a way to ensure that the physical integrity of archived materials and the integrity of the information is not adversely affected. This information has been added to the manuscript (from page 9, line 33 to page 10, line 1):

“Study documents will be archived in CNS in a way to ensure: 1) their integrity once placed within the archive; 2) to prevent from unauthorised access; and 3) to guarantee that they are readily available, upon request, to the competent authorities.”

Discussion

55. The authors expect that use of the risk prompt displays will improve communication - how is this reflected within the outcomes, as communication is not measured directly?

Response: We thank the reviewer for this comment. The aim of this study is to evaluate the feasibility of risk prompt displays designed to communicate risks, which will measure patients’ adherence to the risk prompts. We anticipate that through communication improvement, the risk prompts will improve the awareness and reduce the number of falls, dehydration and pulmonary aspiration events. However we cannot be sure that the effect will come from better information or improved communication and this is not the aim of this study. To clarify this issue in the manuscript, the following sentence of the introduction has been changed (page 3, lines 24-26):

“The used of risk prompt displays by patients, since admission in the nursing home, may improve the access to information and communication between health professionals, which may increase the awareness and reduce the number of falls, dehydration and pulmonary aspiration events in nursing home.”
56. In terms of limitations, this feasibility study will only be conducted in one nursing home. Please comment on this? How will provide you with an idea of feasibility in other nursing home settings?

Response: We thank the reviewer for this comment and we agree. However, once this is an exploratory feasibility study, with no previous similar studies, and being CNS population representative of nursing home usual population, we advocate that this is acceptable for a first exploratory study. According with reviewer’s suggestion the following paragraph has been added to the “Discussion” section (page 10, lines 24-28):

“This study will only be conducted in one nursing home, which could be a limitation. However, CNS population is representative in ages, heterogeneity of diagnosis and symptoms of nursing homes reality. Being this is a protocol for a first exploratory study, we anticipate that running the study in just one nursing home will not compromise the capability to conclude on patients’ adherence.”

References

57. See reference 14 (Folstein et al.) I think something has happened with referencing software, as ”” shows up twice here

Response: We thank the reviewer for this observation. The reference has been corrected in the manuscript (reference 20, page 13, line 32).