D2.4 – Open House Campaign Strategy Report

115985 – MOPEAD

Models of Patient Engagement for Alzheimer's Disease

WP2 – Four different strategies to engage subjects at risk of AD

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Publishable Summary

MOPEAD Run2 includes a pre-screening conducted in the Memory Clinic addressed to the general population. This initiative will be preceded by an advertisement campaign to attract participants.

MOPEAD Run 2 preparation campaign includes several components:

- Design of a pre-screening specific protocol including: inclusion criteria, pre-screening tools, and cut-offs, as well as referral criteria to WP3. These elements have been discussed with the Consortium and no significant modifications have been made in comparison to the Description of Action (DoA)
- Design of a coordinated and harmonised advertisement campaign .
- Training of staff in charge for the administration of the pre-screening protocol. There will be one or more teleconferences organised by FACE to carry out the training. These will take place the month prior to recruitment start.
- Logistics organisation at each clinical site. Provided the basic requisitions described in the DoA are fulfilled, each site will have the flexibility to organise their own Open House campaigns in terms of schedules**,** number of Open House days, action regularity, number of professionals involved, etc.

The OH preparation strategy is based on FACE previous experience but it does also incorporate partners' contributions. Generally speaking, the initial strategy has been well accepted by the entire consortium, reason why there have been no relevant changes compared to what is referred in the DoA. The most evident risk is that in a particular clinical site recruitment may be lower than expected, this problem can be approached by intensifying the advertisement campaign.

Methods

The preparation strategy of the OH campaign consists of the several elements which need to be carried out sequentially in order to guarantee the correct development of the campaign.

- Design of an OH specific pre-screening protocol
- Design of a harmonised and coordinated advertisement campaign
- Training of the staff in charge for the administration of the clinical protocol
- Logistics organisation at each clinical site

Design of a specific pre-screening protocol

This includes inclusion criteria, pre-screening tools to be implemented, the cut-offs for these tools, which will be used in order to consider a pre-screening as positive or negative, and the referral criteria to WP3. These elements have already been described in the Description of Action and have not undergone any substantial variations.

<u>Inclusion criteria:</u>

- Individuals between 65 and 85 years
- Signed informed consent
- No prior diagnosis of cognitive impairment
- No severe visual or hearing impairment which may interfere during the assessment.

Procedures to be carried out by the evaluator are the following in this order:

1. Obtaining informed consent
2. Filling a self-administered questionnaire including social demographic data and past medical history. (the participant must fill it before before being assessed)
3. Asking 3 questions on subjective cognition to the participant. These are the 3 questions:
    a. Do you feel like your memory is becoming worse?
    b. Does that worry you?
    c. How long have you been feeling it?

    These questions have to be asked in an standardized way always at the beginning of the evaluation. The participant will be required to answer to the first 2 questions with yes or no. Regarding the third question if the participant is not able to provide an answer to the evaluator, the latter will need to ask the participant if this is felt for less than 5 years or over 5 years.
4. Initial controlled learning using Free and Cued Selective Reminding Test (FCSRT) (Word version)
5. Administration of the Mini Mental State Examination test (MMSE)
6. Administration of the Hospital Anxiety and Depression Scale test (HADS) (this test is optional)
7. Delayed memory using FCSRT (this subtest is optional)

Referral criteria for WP3 are:

- MMSE score between 20 and 27 or
- A total score in FCSRT below 1.5 the standard deviation below the mean for age and educational level or
- Total score between 1 and 1.5 standard deviation below the mean plus 3 positive responses to the questions on subjective cognition.

*Less than 5 years is regarded as a positive response to question c. Individuals meeting any of the three above mentioned criteria will be referred to WP3. Once the maximal amount of referrals from RUN 2 to WP3 has been reached (33 subjects per country), subsequent individuals participating in the pre-screening will not be referred to WP3, even though they fulfil the referral criteria. Instead of this they will be recommended to see their PCP in order to complete the study as there is a suspicion of cognitive impairment. For this particular purpose, they will be handed a letter addressed to their physician.

Individuals with a MMSE score below 20 should not be referred to WP3, instead of this they will be recommended to see their PCP to complete the study as there is the suspicion of dementia. For this particular purpose, they will be handed a letter addressed to their physician.

Design of a harmonised and coordinated advertisement campaign

A critical part of the Open House strategy is to develop an effective campaign to make known the initiative to potential participants. This is the aim of the advertising campaign that is currently being designed.
One of the specific requirements of the project is that this campaign needs to be applicable almost in parallel in the different sites of MOPEAD. This is a key factor in the campaign because it could strongly affect the results in terms of the obtained engagement.

Therefore, the campaign will meet three criteria. First of all, it will mostly be offline so that it doesn't interfere with the run 1 that is building a strong online campaign. Besides, the strategy will stablish actions which will progressively increase their reach amongst the general public. And finally, the campaign will be applied in parallel at every site of the project when conducting Run 2.

Training of personnel in charge for the protocol implementation at each site

The personnel in charge for the protocol implementation will be the Memory Clinic staff, who has experience in cognitive testing. For this reason it is not required that they take a training in the basic fundamentals of the disease or neuropsychology. The training will be centred in the specific instruments used in MOPEAD:

- Informed consent
- Mini-Mental State Examination (MMSE)
- 3 questions on subjective cognition
- Free and Cued Selective Reminding Test (FCSRT)
- Use of the electronic data base management system, which will be developed for MOPEAD.

There will be a web video conferencing with participation of representatives of all clinical sites and personnel of FACE providing practical examples of each instrument use, and solving any doubts which may emerge.

In case not all the personnel in charge for the protocol implementation can attend this web video conferencing, the attendees should be in charge of training the staff of their Memory Clinic who missed the meeting.

If partners wish so it is possible to schedule 2 identical training sessions on different dates and times so as to facilitate the attendance of most professionals.

We believe it will be convenient that the training is not made too much in advance regarding the recruitment start, for this reason the session or training sessions will be programmed during the month prior to Open House recruitment start.

Logistical organisation at each clinical site

There are common rules which need to be obeyed by all clinical sites, as it is mentioned in the DoA:

- Each clinical site need to perform a minimum of 100 pre-screenings in Run 2, or as many as required for reaching 33 referrals to WP3.

- Recruitment needs to be done within the stipulated timeframe as mentioned in the Description of Action

- The protocol will be implemented by physicians or neuropsychologists experienced in cognitive testing.

- Before recruitment start MOPEAD protocol must have been approved by the Ethics Review Board (ERB), site personnel must have taken the corresponding training, and the advertisement campaign must have been locally implemented according to the previously described common strategy.

Each clinical site will have the flexibility to organise their Open House campaign as they wish, provided that they fulfil the above mentioned conditions. Every site will determine how many OH days and hours wants to implement, also the OH frequency and number of professionals administrating the protocol. Each site will need to designate the administrative staff in charge for answering the calls and scheduling visits for patients. Each site must provide the material resources to conduct the OH activities, e.g. consultation rooms, computers etc.

Each clinical site must take into account that Run 2 activity must run in parallel with WP3, meaning that it must be aligned with the Memory Clinic capacity to receive referrals to WP3. An excessive Run 2 activity at a certain point could generate long waiting lists for patients with a positive pre-screening who will need to undergo a complete diagnostic assessment within WP3.

Discussion

We are presenting here the preparation strategy for the Open House campaign. This strategy is mainly based in the long term experience of FACE in organising Open House Days, but it also includes different suggestions from the clinical partners during the Consortium Meetings and the regular teleconferences.

The strategy has been well accepted by all partners, reason why hardly any modifications have been made on what was reported in the Description of Action. Nevertheless there have been the following minor changes:

- The Hospital Anxiety and Depression Scale (HADS) is no longer considered as compulsory for the pre-screening protocol as this scale is not included within the referral criteria, and it is not administered in the other Runs, which makes it impossible to compare different populations in this regard. For this reason and in order to avoid an excessively long pre-screening and find the most cost-effective model it was decided to eliminate the HADS as a compulsory scale. Nevertheless data on anxiety and depression are relevant for this population group, this is the reason why we have kept this scale as optional, which would eventually allow a subsequent sub-study on the usefulness of this scale in pre-screening.

- The FCSRT delayed recall is no longer a compulsory subtest as it is a time-consuming procedure and controversy is found in the literature on the usefulness of this subtest in adding specificity to the screening, in fact several clinical studies do not use the delayed recall. Nevertheless it will remain as optional, allowing to carry out a subsequent sub-study on the usefulness of the delayed recall in this context.

- DoA mentions that an investigator-meeting will be organised to train the personnel of all 5 sites where the protocol is being administered. After consultation of different options with partners, it has been decided that it is more convenient to do the training in a web video conference. We believe this will be sufficient to guarantee a good training to experienced neuropsychologists, and avoid unnecessary expenses.

- There will be an additional question to the 2 subjective cognition questions mentioned in the DoA, by request of the Consortium members who are renowned experts in subjective cognitive decline. The time frame when subjective cognitive decline takes place has a prognostic value, this is why it is useful to take it into account.

Based on FACE experience in conducting Open House Days we are confident about that this will be a feasible program and that the required figures will be reached by any of the 5 clinical sites.

The most evident risk is that we get a recruitment rate lower than expected. This problem can be solved by intensifying the advertisement campaign at the sites where this might be required.