MOTIVATIONAL INTERVENTION FOR ELDERLY PEOPLE IN GERIATRIC POST-STROKE REHABILITATION DURING ADMISSION AND IN TRANSIT TO THE HOME (IMAGINE)

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1. Summary of the project

Background: Rehabilitation is crucial for reducing stroke-associated disability. Motivational interviewing (MI), a person-centered intervention with the aim of empowering and motivating the patient, could improve stroke rehabilitation in older people.

Objectives: The main objective of the IMAGINE project was to evaluate the impact of MI, associated with standard geriatric rehabilitation, on functional improvement at 30 days measured with the Functional Independence Measure (FIM), compared with standard geriatric rehabilitation alone, in geriatric patients admitted for post-stroke rehabilitation. As secondary objectives, the impact on physical activity, physical function, self-efficacy, sense of coherence, safety, cost-utility and experience of the participants, caregivers and professionals involved was analyzed.

Methodology: A pragmatic multicentre randomized clinical trial was carried out in three geriatric rehabilitation services from different centers in Catalonia. Specifically: at the Consorci Sanitari Integral in Hospitalet, at the Hospital Santa Maria in Lleida, and at Parc Sanitari Pere Virgili in Barcelona. The participants in the study were older people admitted to any of these three centers after a mild-moderate stroke, without previous dementia, post-stroke severe cognitive impairment or delirium on admission, and without previous severe disability, aphasia or other communication limitations or terminal illness. Finally, between July 2018 and June 2021 261 patients were included in the study, who were randomized between the control group (135) and the intervention group (126) using a web application developed for this project. Control group's patients received written information on the benefits of exercise in addition to the standard rehabilitation that is performed in each hospital. In addition to this standard rehabilitation the patients in the intervention group, received a maximum of 5 and a minimum of 4 sessions of structured MI, implemented by nursing staff linked to the project, duly trained in the use and implementation of MI in a health context, and specifically in population with stroke. A professional expert in MI supervised part of these sessions. The objective of these sessions was for the professional and the patient to develop a shared work plan and reinforcement of the rehabilitation carried out in the reference hospital, according to the objectives, needs, preferences and capacities of these patients. Physical activity in the hospital was measured with accelerometers

(activPAL®) and questionnaires (BPAAT). Different questionnaires and scales aimed at evaluating physical function (FIM, Barthel, Lawton, mRS, FAC, Trunk Control test), clinical status, physical and cognitive frailty (MNA-SF, Charlson, drug use, SPPB, MOCA) emotional state (EBMWE, Yesavage), social support (DUKE), self-efficacy (GSE), and perceived quality of life (EuroQoL-5D) were also administered. Likewise, the cost-utility of the intervention was evaluated using the cost/QALY indicator. As a complex intervention, an evaluation of the process and experience of participants, caregivers and professionals was also carried out using qualitative methods.

2. Results

a) Statistical analysis of the main variable and secondary outcomes

Improvement in functional status was the main objective of the IMAGINE study. The data show that functional status did improve during the study period, but in both groups, intervention and control, without statistically significant differences. A clinically relevant and statistically significant improvement was observed at 30 days, of a mean of 16.29 points on the FIM scale (95% CI: 14.18 to 19.40). In addition, functional status performance still increased after discharge from the rehabilitation center, with an overall improvement seen at 3 months of 23.3 points on the FIM (95% CI 20.36 to 26.24). These gains in functional status correlate with other physical improvements in terms of physical performance and functional autonomy. Autonomy in basic activities of daily living (BADLs) measured with the Barthel index (BI) shows a clear increase at 30 days, and continued to increase after discharge. At 3 months, 50% of the participants had a BI of 70 or more. Likewise, the percentage of independent or minimally dependent individuals for ABVDs increased substantially at 30 days, from 22.4% to more than 50%, and continued to increase at 3 months, to more than 60% of the participants. Autonomy in instrumental activities of daily living (IADLs) also improved during the study period, although it is understandable that the greatest improvement was observed after hospital discharge (when these activities are performed in real life). Participants have greatly improved their physical performance as assessed by the SPPB scale, with clinically relevant increases at 30 days (from a mean of 2 points to a mean of 3.9 points) and at 3 months (achieving a mean of 5 points). Likewise, the percentage of participants with good physical performance went from 8.8% at admission to 22.5% at 30 days and 33.7% at 3 months. The percentage of participants

with poor physical performance decreased from 81.2% at entry to 58.4% at 30 days and 48.4% at 3 months. Ambulation and walking speed, which are part of physical performance, improved steadily over the study period. The percentage of non-ambulatory individuals (FAC=3) decreased from 41.5% to 21.4% at 30 days and to 12.8% at 30 months. However, the walking speed of the ambulatory participants was on average quite low, even at 3 months. In contrast, no changes were detected in self-efficacy during the study period, nor in quality of life or mood.

EFFECT OF THE INTERVENTION (MI) ON THE REHABILITATION PROCESS

The gains in functional status observed during the study period were similar in both groups. The implementation of a motivational interviewing intervention showed no clinically relevant improvement in functional status measured with FIM, either at 30 days or at 3 months compared to standard geriatric rehabilitation alone.

OTHER IMPACT MEASURES

Participants' degree of physical activity assessed at 30 days, did not vary between the two intervention groups with respect to the percentage of daily time spent walking, standing or sitting. Physical performance was evaluated in terms of walking speed and SPPB. Participants improved their walking speed during follow-up, and this improvement was greater in the intervention group. However, no statistical or clinical differences were observed between the two intervention groups at the time of the main 30-day study. Similarly, no statistical or clinical differences in physical performance measured with the SPPB scale were observed between the two intervention groups at the primary study time point of 30 days. The participants did not show an increase in their self-efficacy during the study period. Self-efficacy remained constant at both endpoints (30 days and 3 months) for both groups.

SAFETY

The procedure was safe for stroke survivors. Serious adverse events (new cerebrovascular events or events requiring transfer to an acute hospital or emergency department) were rare and similarly distributed between the intervention and control groups. The most frequent adverse event was the incidence of falls, but these were observed to be similar in both groups.

b) Results of economic analysis:

This analysis aimed to assess the cost-utility of a non-pharmacological intervention consisting of a set of motivational interviews conducted by nursing professionals. First of all, it has been verified that there are no differences in the characteristics of the sample between control and intervention groups. In relation to cost, the data suggest that there are no differences in the use of resources, between the control and intervention groups as a consequence of the intervention. Direct costs are approximated at €12,688 in total, or €98.35/patient. In relation to the utility measure, although the patients did vary their EUROQOL index score at the different time points, there was no significant difference in terms of the intervention. Thus, an improvement in the target variable cannot be attributed to the intervention. It is observed that there is a significant impact of gender when obtaining the EUROQOL index score, but this impact cannot be attributed to the intervention that has been carried out on the patients. Thus, it is concluded that the intervention has a positive incremental cost, while no impact is observed on the outcome variable.

Among the strengths of the economic analysis, we highlight the correct randomization of the sample and the remarkable diversity of variables. Among the limitations are the very short time horizon of the economic database (3 months), the variation in the variables collected over time (relevant variables such as the use of a wheelchair are recorded at the first time point, but not in the second), and the high number of missing values, which restricted the validity and usefulness of the statistical tests.

c) Results of the qualitative analysis:

Regarding the global context, the pandemic affected the context of the intervention itself, above all due to the restrictions on family visits during hospital stays.
"Then the coronavirus came, and. then I came back, they reopened and I was there for 20 days, but it has also become more complicated and. they restricted the number of people who went there." (patient, 74-year-old man).

The personal and social situation of the patients prior to the intervention has influenced how they have been able to receive it, with regard to family support, educational level, the severity of the stroke and the effects it had caused (especially in the case of aphasia and cognitive impairment).

"A patient who started out with a problem of aphasia or dysarthria, who in the end had recovered much more language, is not the same, right? (Motivational Interviewing nurse)".

On the part of the professionals who carried out the MI intervention, initial training and supervision of how they implemented MI was key.

"The nurses highly valued this time spent with the patients and they valued it very much, they were surprised at how this type of treatment was for the patient. it allowed them to reach the patient, understand him more, be more. be more empathic" (MI trainer)

"At least I felt supported. (.) That at any time I could ask or say or tell, right? That someone was there to be able to do it" (nurse motivational interviewer)

Regarding the implementation of the intervention itself, two differentiated components clearly emerged: the relational component between patient and MI nurse-facilitator and the personalization component of activities between sessions as reinforcement in the rehabilitation plan (for example, complementary exercises to the physiotherapy and rehabilitation sessions of the center).

"(The staff professionals) can contribute but not as specifically as when you expressly go to do this interview, when you spend half an hour, three quarters, an hour. whatever the patient needs, right?" (Motivational Interviewing nurse).

"That building, well all the buildings are, they're a ring. And I circled the entire building four times." (patient, 92-year-old man).

The team of professionals perceived the lack of integration between the MI professional and the interdisciplinary team as a limitation.

"I've missed the feedback, you know? It's been like.(.) It's like. the intervention has been performed on the patient, the patient has received a series of inputs, right? He's come here, he's done his therapy and stuff, right? But… we haven't had the feedback, that perhaps we could govern ourselves, right? When performing the intervention with

the patient. Yes, I have missed that.(.)…it's because of schedules too, eh! The (motivational) nurses come in the afternoon and we haven't been able to… it's not their fault, no, on the contrary. If we have been able to catch some, we have talked about it, eh? I'm telling you this too, right? But of course, due to schedules. due to dynamics. due to many things we have not had that collaboration, although it is true that sometimes we have been able to do so. Sometimes yes, and so how about that, huh? What do you think? But it was like something more spontaneous, not something regulated. I don't know." (staff physical therapist)

Several barriers and facilitators were identified and the most relevant ones are listed below. It is important to highlight the importance of receiving support from a caregiver who is available, who feels prepared and capable of caring and who could have been involved during the rehabilitation and in the MI (they are present in the interviews or support in carrying out the agreed exercises). *"She (the MI nurse) came up with the idea, I told my wife, and the three of us did it." (patient, 75-year-old man).* In addition, a key element for the implementation was the patients' own vision and experience regarding their role in their daily environment and how they face returning home.

The impact mechanisms, which explain why the intervention could have certain effects, are: satisfaction and acceptance of the components and characteristics of the intervention; satisfaction and connection with the motivating professional; support from regular rehabilitation professionals; the involvement of family members during rehabilitation and adherence to the rehabilitation and MI process.

"I think that everything I contributed was a little more the emotional part, right?" (MI nurse).

"People come very lost, with more family and more family support they are even more motivated." (MI nurse).

The impacts perceived by patients, relatives and professionals in the patients themselves have been at the mental level (for example, improvement of motivation and empowerment) and at social level, meaning changes in lifestyle and facilitation of the transition to discharge.

Regarding the vision of the continuity of the intervention that the professionals had, proposals have been identified both to have a single professional trained with this role (identifying nursing above all as a profile) and the suitability of training the entire staff team and that each will incorporate this view of MI in their interactions with patients. The need to integrate the MI figure with the interdisciplinary team was unanimous. The professionals pointed to the adequacy and need for MI also for other patient profiles beyond stroke.

"I think that the basic thing would be that, to train the entire team. That is, nurses and assistants. Those who are there day by day with the patients." (staff nurse)

3. Relevance with possible future implications

Although MI has shown efficiency in promoting physical activity and improving rehabilitation outcomes in the literature, in our sample it has not been possible to observe an impact on functional improvement. More research is needed to find better ways to implement Motivational Interviewing in rehabilitation centers and which types of older stroke survivors may benefit most from non-pharmacological interventions, such as Motivational Interviewing, to reduce associated disability. In any case, the tool was valued very positively through the qualitative study as a training instrument for nurses to have more resources and greater security in shared decision-making with patients, and the patients themselves also valued it positively. This instrument, therefore, could be considered as a useful tool for basic training, although it is not effective as a single and individualized intervention.

Given the longitudinal design of the study, it provides a great deal of information on the evolution of elderly people after a stroke, both at a physical level and at a cognitive and affective level. Such detailed information may have implications in clinical practice when assessing prognostic factors and post-stroke functional/cognitive/affective trajectories, and personalizing rehabilitation and convalescence after a stroke to maximize resources and obtain better results. More studies are needed in this geriatric population, which has been historically understudied.

So, despite not being able to support the application of MI as an intervention tool on its own, in these patients it can be a good training tool for health professionals, with the aim of improving shared decision-making. The qualitative analysis has also allowed us to see which elements may have failed when carrying out the intervention and, therefore, will allow us to improve the design of future non-pharmacological interventions in this type of person.

The project has also made it possible to expand knowledge and train professionals on Motivational Interviewing. This same tool has been transferred to other types of complex interventions, such as the +ÀGIL Barcelona program, which is aimed at preventing disability in frail people and is implemented as a stable and continuous program in a basic health area from Barcelona.

4. Generated scientific bibliography

A publication in the journal BMC Geriatrics (1st quartile Geriatrics and Gerontology from 2013 to date).

Citation: Neus Gual, Laura Mónica Pérez, Carmina Castellano-Tejedor, Pilar Lusilla-Palacios, Judith Castro, Luís Soto-Bagaria, Laura Coll-Planas, Marta Roqué, Ana Belen Vena, Benito Fontecha, Jose M Santiago, Eva Månsson Lexell, Carlos Chiatti, Susanne Iwarsson, Marco Inzitari. IMAGINE study protocol of a clinical trial: a multi-center, investigator-blinded, randomized, 36-month, parallel-group to compare the effectiveness of motivational interview in rehabilitation of older stroke survivors, BMC Geriatr. 2020 Sep 4;20(1):321. Doi: 10.1186/s12877-020-01694-6