

Assessing the Outcome of Mobility Assistive Technology (OMAT) in Daily Living: Preliminary Results in an Italian Sample

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Abstract. The World Health Organization has defined assistive technologies (AT) as the fourth pillar of global health and supported identifying AT outcomes among the five top priorities in AT research. In this framework, the research study OMAT (Outcomes of Mobility Assistive Technology in rehabilitation pathways) was developed by Fondazione Don Carlo Gnocchi. The OMAT study aims to develop and test the applicability of a model of rehabilitation pathway related to prosthetic interventions in the field of mobility: a multidisciplinary assessment of patients' needs and expectations was made at baseline and after an adequate period of use of the prescribed assistive devices in everyday settings. To date, the study is ongoing. The present work aims to show the preliminary results of the OMAT research study, in particular its primary outcomes. Specifically, OMAT AT outcome assessment consists of 1) perceived effectiveness of assistive mobility products, 2) satisfaction of the intervention and 3) possible changes in quality of life. Among the recruited subjects (N = 32), most patients (87.5%) received only one mobility assistive product, especially bimanual self-propelled wheelchairs. Patients used the received mobility assistive products for 3-6 months, with a good frequency (few-days/ week) and moderate support. Preliminary results showed a positive impact of assistive mobility products in terms of perceived effectiveness, intervention satisfaction, and quality of life. Interestingly, patients showed improved quality of life, showing a significant decrease of the severity degree in problems identified at baseline evaluation. Further studies will be conducted to replicate these promising results in a larger sample.

Keywords: Mobility assistive technologies \cdot AT assessment \cdot AT service delivery \cdot AT outcome measurement \cdot Rehabilitation pathways

1 Introduction

The World Health Organization (WHO) has defined assistive technologies (AT) as the fourth pillar of global health (launch of the GATE initiative "Global Cooperation on Assistive Health Technology", "Priority Assistive Products list", 2016), along with drugs, vaccines, and medical devices. Specifically, the assistive products must be considered a

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necessary component to maintain or improve the person's functioning. However, only a minority of countries in the WHO European Region have comprehensive monitoring mechanisms for assistive technology in terms of evaluating needs for assistive technology and assessing the impact on disease in the patient's life (World Health Organization 2021). For this reason, AT outcome evaluation has been indicated by the World Health Organization as among the five top priorities in AT research (Gutenbrunner et al. 2015).

Within the Italian National Health Service, the AT service delivery process is already structured in steps: assessment, prescription, authorisation, delivery, while inspection and follow-up are still not regulated and left to the initiative of service providers.

Over the years, several works have focused on the high rate of abandonment of received AT due to changes in health conditions (Lenker and Paquet 2004) or failure of AT to meet patients' needs and expectations (Federici et al. 2016). These observations led to think that the assessment of the prosthetic intervention's effects must be carried out "on the field" after a reasonable time of use of the assistive products (APs) by the users in their real living environment (Salatino et al. 2016).

In this framework, the research study OMAT (Outcomes of Mobility Assistive Technology in rehabilitation pathways) was developed by the Italian research rehabilitation institute "Fondazione Don Carlo Gnocchi" (FDG), funded by the Ministry of Health (2020–2022). The OMAT project aims to develop and test the applicability of a new model of rehabilitation path related to assistive technology interventions in the field of mobility that, after an initial multidisciplinary evaluation of patients' needs and expectations, also includes inspection and follow up phases with outcome assessment after an adequate period of use of the prescribed AP in everyday settings. This research study is ongoing; the present work aims to show its preliminary results.

2 Methods

To date, seventy-five patients that needed mobility assistive devices were recruited at two centres of Fondazione Don Carlo Gnocchi ONLUS: "IRCCS Santa Maria Nascente" in Milan and "Spalenza" in Rovato (Brescia). The recruited patients were classified by the International Classification of Disease (ICD-9).

The research protocol includes two sessions at a distance of 3/6 months:

- 1) baseline standard clinical evaluation and prescription of the mobility APs (T1)
- experimental follow-up session in which patients are re-contacted after 3–6 months of use of received AT in the real living environment (T2).

Overall, the research protocol involved a standard clinical evaluation with the addiction of validated AT outcome assessments instruments selected on the basis of a previous literature review (Salatino et al. 2018).

In detail, all participants underwent a baseline evaluation (T1) of the state of health/disability, made by a clinician, consisting of Barthel index 20, to evaluate autonomy degree in daily life activities (Mahoney 1965), Mini-Mental State Examination (MMSE) (Folstein et al. 1975; Measso et al. 1993), to assess the global cognitive functioning and Modified Cumulative Illness Rating Scale, to measure any comorbidities

(CIRS) (Linn et al. 1968). According to the clinical interview and cognitive screening, the health practitioner decided whether the patient would be able to provide responsive answers to the self-reported questionnaires; on the contrary, the caregiver was involved. Therefore, the questionnaires "36-item Short Form Health Survey" (SF-36) (Ware et al. 1992) or "Adult Career Quality of Life Questionnaire" (AC-QoL) (Elwick et al. 2010) were administered to evaluate the quality of life involving patients or caregivers. Moreover, the subjects completed the IPPA (Individual Prioritised Problems Assessment) (Wessels et al. 2004) first questionnaire (IPPA1) to assess the severity of the problems they expected to solve by the prescribed assistive solutions. After that, patients received different mobility APs (e.g., manual or powered wheelchairs, seating systems, walkers, hoists). Conventionally, we have used the International Standard ISO 9999:2016 as reference classification systems for assistive devices.

The study is ongoing. Currently, thirty-two patients have been evaluated at followup (T2) after 3–6 months of using products in the real living environment. At follow up, participants performed the same quality of life scales and IPPA second questionnaire (IPPA2) to detect how the user's expectations had been met with assistive solution received. Moreover, participants evaluated the received assistive solutions in terms of satisfaction through the QUEST questionnaire (Quebec User Evaluation of Satisfaction with Assistive Technologies) (Demers et al. 2000). In this work, we report the preliminary data on these 32 patients. Outcome assessment instruments involved: 1) perceived effectiveness of assistive mobility products evaluated by IPPA (IPPA = IPPA1-IPPA2); 2) satisfaction of the intervention by QUEST and 3) possible changes in quality of life.

3 Statistical Analysis

All statistical analyses were conducted using Jamovi software 1.6.23. Descriptive statistics included frequencies, Median and Interquartile Range (IR) for categorical variables and Mean and Standard Deviation (SD) for continuous measures. Moreover, T-tests for paired samples were calculated to investigate longitudinal changes in the primary outcome measures. Pearson correlation was used to evaluate any relationship between the outcome assessment instruments' results. A statistical threshold of p < 0.05 was considered statistically significant.

4 Results

The recruited subjects (N = 75) are predominantly female (M:F = 32:43) with a mean age of 74.3 years (SD = 16.7, min = 18, max = 94). At the baseline evaluation, patients showed an average score on the Barthel scale of 8.63 (SD = 4.18) and 0.78 (SD = 0.36) on the severity index of CIRS. 48% of patients (n = 36) received a bimanual self-propelled wheelchair (ISO:122203). Only ten patients have received two mobility APs.

Thirty-two patients completed the research protocol (follow-up-T2). Table 1 reports the main demographic and clinical characteristics of these patients. The subjects are predominantly females (M:F = 9:23) with a mean age of 71.7 years (SD = 19.1, min = 18, max = 94) and education near to 4 (9–13 years). The patients were classified

by the International Classification of Disease (ICD-9): most of the patients (53.1% - N = 17) belonged to "Diseases of the nervous system and sense organs" (320–389) followed by 18.8% in "Musculoskeletal and Connective Tissue Diseases" (710–739), and 9.4% in "Diseases of the circulatory system" (390–459). Regarding the evaluation of health/disability status, patients showed an average score on the Barthel scale of 8.63 (SD = 3.78 - range 0-19), with one patient that showed an absence of autonomy in carrying out all everyday activities, such as bathing, transfers, mobility, stairs (Barthel score = 0) and two patients with independence in the most of daily life activities (Barthel score ≥ 15). Moreover, 28 patients (87.5%) presented at least one comorbidity, particularly hypertension (50%) and disorders in the sense organs (40.6%), musculoskeletal-skin system (93.7%) and nervous system (62.5%). However, patients exhibited a low average score of 0.78 (SD = 0.33 - range 0.23-1.46) on the severity index of CIRS.

Table 1. Clinical and demographic characteristics of the sample. N = Number, SD = Standard Deviation, M = Males, F = Female, IR = Interquartile Range, CIRS = Cumulative Illness Rating Scale, SI = Severity Index.

| | | Patients [N = 32] |
|---------------------------|-------------|-------------------|
| Age (years) | Mean (SD) | 71.7 (19.1) |
| Sex (M:F) | | 9:23 |
| Education (years) | Median (IR) | 4 (3-4) |
| Barthel total score (/20) | Mean (SD) | 8.63 (3.78) |
| CIRS_SI | Mean (SD) | 0.78 (0.33) |

Most of the patients (87.5%) needed only one mobility assistive device. Specifically, 46.9% of patients (n = 15) received a bimanual self-propelled wheelchair (ISO: 122203). The other products included rollators and walking chairs (ISO: 120606 and 120609 respectively) (15.6%), motorized mobile stair climbers (ISO: 121703) (9.4%), propulsion unit for manual wheelchairs (ISO: 121809) (6.3%) and other wheelchairs (18.8%, e.g., power wheelchairs (ISO: 122306)). Patients used the prescribed mobility assistive products for 3–6 months, with a good frequency (median = 4 - a few days a week) and moderate support (median = 2 - assistance required for certain operations). Specifically, only two patients did not use the prescribed mobility assistive devices, while 37.5% used them everyday. Among the most used APs (frequency \geq 4), the bimanual self-propelled wheelchair appeared the most utilized (47.4%), followed by rollators and walking chairs (15.8%). After the clinical interview and cognitive screening, 19 patients and 13 caregivers completed the self-evaluated questionnaires.

Interestingly, a comparison between patients that completed or not the self-evaluation questionnaires has shown the absence of significant differences in terms of number $(X^2(1) = 2.24, p = 0.135)$ or type $(X^2(9) = 8.92, p = 0.445)$ of prescribed APs. On the contrary, a significant difference emerges in the frequency of use and need for assistance with the first group that used more often the received APs (p = .003: median 5, everyday)

vs 3, a few days a month) and with less support (p = .045: median = 2, moderate vs 3, high).

As regards the quality of life, patients obtained a significant improvement (t(18) = -2.650, p < .05) in the "health change" domain of SF-36 after using assistive products. On the contrary, an aggravation appeared in "physical function" and "general health", two domains strongly influenced by numerous factors (e.g., environmental stressors). However, patients showed no significant worsening in the "role emotional", "social function", "pain", "role limitation", "energy", and "emotional" domains. In evaluating their quality of life, caregivers showed the absence of significant worsening in AC_QoL total score and domains, except for "money matter". Specifically, they obtained at T2 a mean total score of 76.31, confirming a mid-range reported quality of life. Moreover, they confirmed a mid-range reported quality of life in all domains, except "caregiving stress," in which they obtained a better result (mean = 11 ± 3.98 – the high-reported quality of life).

Figure 1 shows scores obtained by patients or caregivers in the pre-post evaluation of the perceived effectiveness of assistive mobility products evaluated by IPPA1 and IPPA2.

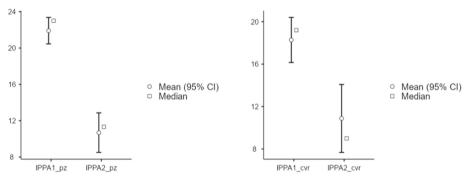


Fig. 1. Scores obtained by patients or caregivers in the IPPA scale first interview (IPPA1) and IPPA scale second interview at follow up (IPPA2). IPPA = Individual Prioritised Problems Assessment; pz = patient; cvr = caregiver

Results showed a significant difference between the IPPA first questionnaire (IPPA1) and IPPA second questionnaire (IPPA2) both for patients (t(18) = 10.88, p < .001) and caregivers (t(12) = 4.71, p < .001), underlying a good perceived effectiveness of assistive mobility products. Participants provided, in mean, lower scores for IPPA at T2 evaluation (IPPA_pz = 11.2 ± 4.5; IPPA_cvr = 7.4 ± 5.67). Interestingly, all patients underlined good perceived effectiveness of assistive mobility products, with a significant decrease of the degree of severity in problems identified at baseline evaluation. Furthermore, only one caregiver supported the presence of a slight worsening (IPPA_crv = -3).

Furthermore, all participants (patients and caregivers) evaluated the satisfaction of the intervention by QUEST, showing high scores in total score (respectively, mean = 4.61 ± 0.41 and 4.34 ± 0.60) and the evaluation of product (respectively, mean = 4.55 ± 0.47 and 4.28 ± 0.83) and service (respectively, mean = 4.75 ± 0.48 and $4.44 \pm$

0.53). Patients provided a high satisfaction (>4) of the intervention due to all products. Caregivers provided good scores to all products (total score \geq 3.50), particularly bimanual self-propelled wheelchairs (mean = 4.52) and rollators and walking chairs (mean = 4.70/4.92).

Finally, no significant correlations (p > .05) appeared between IPPA scores, QUEST scores and frequency of use both for patients and caregivers.

5 Conclusions

The research study OMAT (Outcomes of Mobility Assistive Technology in rehabilitation pathways) developed by Fondazione Don Carlo Gnocchi fits perfectly with WHO guidelines that inserted the AT outcome among the five top priorities in AT research (Gutenbrunner et al. 2015). Over the years, several researches focused on the high rate of abandonment of the received AP due to patients' health condition improvement or worsening (Lenker et al. 2004) or failure of the assistive device to meet the patient's expectations (Federici et al. 2016). Therefore, it is clear that measuring the prosthetic intervention's effects must be carried out "on the field" after a reasonable time of use of the APs by the users in their real living environment (Salatino et al. 2016). This work proposes the preliminary results of the assessment of the impact of assistive mobility products using a model of rehabilitation path related to assistive technology interventions that includes clinical and outcome assessment instruments in addition to the standard delivery process of AT currently envisaged by the Italian national health system. In particular, the project proposes to add, after an initial multidisciplinary evaluation of patients' needs and expectations, an outcome assessment phase (follow-up phase) after an adequate period of use of the prescribed APs.

Therefore, thirty-two patients underwent a multifaceted evaluation at baseline, and after 3-6 months of use of mobility assistive devices in the real living environment to evaluate: 1) perceived effectiveness of assistive mobility products evaluated by IPPA; 2) satisfaction of the intervention by QUEST and 3) possible changes in quality of life. Our sample is heterogeneous in terms of demographic (i.e., age, sex and education) and clinical characteristics (i.e., cognitive, functional and clinical health/disability status), allowing us to evaluate outcomes, including different possible clinical conditions that could need assistive mobility intervention. Most of the patients (87.5%) only required one mobility assistive device, particularly bimanual self-propelled wheelchair (46.9%), rollators and walking chairs, motorized mobile stair climbers, propulsion unit for manual wheelchairs and other wheelchairs. Overall, patients used the prescribed mobility assistive products for 3–6 months, with a good frequency and moderate support. Preliminary results of the OMAT research study showed the positive impact of assistive mobility products in all primary outcome aspects. Most of the participants (96.88%) supported the good perceived effectiveness of assistive mobility products evaluated by IPPA, showing a lower degree of severity in problems identified at baseline evaluation. Only one caregiver supported the presence of a slight worsening. Moreover, patients and caregivers showed an improved quality of life as evaluated by self-questionnaires. Specifically, patients obtained a significant improvement in the "health change" domain of SF-36 after using assistive products, and caregivers obtained a better result in the "caregiving stress" domain. Furthermore, the absence of significant worsening appeared in other quality of life domains (e.g., social functions, pain, energy), except for "physical function" and "general health", two domains strongly influenced by numerous factors (e.g., environmental stressors). In light of these results, it will be important to evaluate the functional and clinical status of the patient also at the follow-up to investigate any other conditions that may occur in everyday life. These promising results in improving quality of life and significant change in problems identified at baseline evaluation supported the need to consider the APs a primary component to maintain or enhance the person's functioning (launch of the GATE initiative "Global Cooperation on Assistive Health). Finally, the preliminary data showed that all participants evaluated the overall intervention as highly satisfactory, both in terms of product and service. Interestingly, patients provided a high satisfaction (>4) of the intervention due to all products.

Overall, the preliminary results of the OMAT research study showed the applicability of selected outcome assessment instruments in the clinical context and a positive impact of assistive mobility products in terms of perceived effectiveness, satisfaction of the intervention and quality of life both for patients and caregivers.

In conclusion, the model of rehabilitation path in the field of mobility, which includes an initial evaluation of patients' needs and expectations and an outcome assessment after a period of use of prescribed APs in everyday settings, could allow to overcome the lack of comprehensive monitoring mechanisms for assistive technology in the WHO European Region (World Health Organization 2021), also going beyond the standard delivery process of AT currently envisaged by Italian National Health Service.

Further studies will be conducted to replicate these promising results in a larger sample.

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