Ja.me
tremor control assistant

AAL PROGRAMME

SCP - FINAL
PROJECT REPORT

Report date	29/03/2021

PUBLISHABLE PROJECT INFORMATION (TO BE USED BY AALJP)

1A. PROJECT	
Project full title	JAME: combining biomedical technologies and design to control disabling symptoms in ageing people with chronic neurodegenerative diseases.
Project acronym	JAME
Project No.	*AAL-2019-6-105-SCP*
Project Website	https://jame.units.it/
Project duration	• Starting date: *01/03/2020* • Termination date: *28/02/2021*
Coordinator's name and details	Full name: Sara Francesca Renata Marceglia E-mail address: smarceglia@units.it Telephone number: +39 040 5583450

1B. PROJECT PARTNERS					
No.	**Partner organisation name**	**Partner org. acronym**	**Type***	**Project costs: Public grant in Euro**	**Project costs: Partner own contribution in Euro**
1 (coord.)	Università degli Studi di Trieste	UNITS	University	92.760,00	23.190,00
2	Feature Jam	FJ	SME	41.920,80	14.999,20
3	Foundation for the Study of Neuroprotection and Neuroplasticity	FSNN	Research Organization	0,00	0,00
4	*Fundación de FIHM investigación HM Hospitales*	FIHM	Research Organization	49.973,00	0,00
5	*BOONE*	BOONE	Enterprise	24.340,00	24.341,00
6	*Fondazione IRCCS POLI Ca' Granda Ospedale Maggiore Policlinico*	POLI	Research Organization	66.250,00	0,00

1C. PUBLISHABLE PROJECT RESULTS SUMMARY *(1 PAGE)*

Jame is a wearable device aimed to control hand tremor in a non-invasive way, and able to continuously collect tremor data in order to monitor patients for better disease management. In this AAL project, starting from an initial functional prototype, we designed the new Jame that consists of a newly designed device, presently under final stages of development (the first functioning prototype will be available soon), and of a telemonitoring, for which we developed a mockup-app and a preliminary implementation.

The uniqueness of the Jame concept is based on three main characteristics: (1) Jame should not be a stigmatizing device that could make the user uncomfortable, (2) Jame should not act for a limited time but should be a non-invasive and real-time treatment that helps the patient when needed, and (3) it should not work for a single selected action but should allow patients to get their own normal life back, both in the simple daily routine and in the working environment. Jame is targeted to patients with chronic neurodegenerative disorders experiencing tremor, a symptom that cause the loss of autonomy even in the early stages of the disease; tremor is a common feature in Parkinson's disease, PD, (6 million worldwide) and Essential Tremor (eight times more common than PD, affecting 1% of worldwide population) and its treatment is not fully satisfying. In fact, non-invasive treatments for tremor are lacking and existing commercial devices are highly stigmatizing for patients.

Tremor causes changes in patients' lives: almost 50% of patients are not able to perform their job anymore and 20% of patients can lose it. Jame primarily addresses patients who are still at work and want to act and stay in public by reducing the embarrassment and by increasing their self-confidence.

Unfortunately, the project was fully developed under the pandemic emergency (started March 1st, 2020 and ended February 28th 2021). The planned involvement of end users during the project was strictly limited due to sanitary restrictions. The Consortium was anyway able to involve some primary end-users in dissemination activities, in the UTE analysis and in the clinical trial aimed to assess the efficacy of the treatment.

As shown in our end-users analysis (despite being conducted in an emergency situation), all patients interviewed were enthusiastic about the Jame concept. High expectations of considerable impact on patients' lives were observed regarding wearing Jame, especially for helping them perform normal daily activities (almost 80% of interviewed users), and for being in public without shaking (more than 50% of interviewed users). In addition, we anticipate that the additional telemonitoring system, allowing continuous monitoring of tremor and providing personalized assistance, would help increase treatment effectiveness and disease control, also when it is impossible to follow the traditional method of diagnosis and treatment based on frequent in person visits. As a final research advantage, in terms of big data, once available as a product, Jame will collect a large amount of optimized clinical and epidemiological data that will be available for further studies. All the patients involved in our end-user analysis want to be involved for future pilot studies using the wearable device.

As technological innovation, during the project we developed the core blocks of Jame: (1) the tremor-detection block that was improved and tested by using upper limb movements recorded while patients were executing some activities of daily living (ADL) from selected clinical scales, using wearable IMU sensors; first, we used an available dataset coming from scientific literature, then, we validated it thanks to data collected by the Consortium. Preliminary results show a detection accuracy of above 90% in both the preliminary study with literature data, and in the validation study with newly recorded data. Such results, even though with some caveats, are encouraging for the Jame adoption in real-life scenarios. 2) The non-invasive stimulation to treat tremor was applied to a pilot group using a commercial CE-marked device, and tremor suppression was estimated through tri-axial accelerometer recordings acquired from an inertial sensor placed on the back of the hand; preliminary results show a tremor suppression (baseline versus stimulation) of 24% in resting tremor at 4Hz in the more affected hand and an attenuation in the action tremor (pronation-supination task) of 64% at 4 Hz, 55.59% at 5 Hz, 92.45% at 6 Hz and 87.35% at 7 Hz. The clinical trial is still recruiting other patients to increase our internal knowledge and the external reliability. As a design innovation, the new visionary design was fully developed thanks to expert designers, and was then validated through the end-users analysis.

Considering our present results, we plan a time-to-market of 3 years that will include the development of a finalized JAME device, with essential requirements testing and clinical data on efficacy and usability, and the CE mark process under the new MDR. During the project, we identified a first business plan and market approach that requires future activities to define our strategic network with neurologists and patient's organizations and a more detailed business plan for the first two years on market. Even though the project ended, the Consortium strongly believes in the Jame idea, and plans to further continue with the activities, until Jame will be ready for patient's use.