Effect of monitoring frailty through a mobile application and a sensor kit to pre-vent functional decline in frail and prefrail older people: the FACET pilot ran-domized control trial.

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Abstract

Background: Frailty represents a state of susceptibility to stressors and constitutes a dynamic process. Untreated, this state can progress to disability. Hence, timely detection of alterations in patients' frailty status is imperative to institute prompt interventions and impede progression. With this aim, the FACET technological ecosystem has been developed to provide clinically gathered data from the home to a medical team for early intervention.

Objective: To assess whether the FACET technological ecosystem prevents frailty progression and improves frailty status, according to the Frailty Phenotype and FTS-5, at 3 and 6 months of follow-up.

Methods: This randomized clinical trial involved 90 older adults aged 70 years or above meeting 2 or more Fried Frailty Phenotype Criteria, having 4 or more comorbidities, and having supervision at home. The study was conducted between August 2018 and June 2019 at geriatrics outpatient clinic in Getafe University Hospital and Albacete University Hospital. Participants were randomized into a control group, receiving standard treatment, and the intervention group, receiving standard treatment along with the home monitoring system (FACET). The system monitored functional test at home (gait speed, chair stand test, frailty status and weight). Outcomes were assessed using multivariate linear regression models for continuous response and multivariate logistic models for dichotomous response. P-values lower than 0.05 were considered statistically significant.

Results: The mean age was 82.33 years old, with 27.78% being male. Participants allocated to the intervention group showed a 73% reduction in the risk of deterioration by FTS-5 score (p-value = 0.04) and 92% lower likelihood of worsening by 1 point according to Fried Frailty Phenotype Criteria compared to the control group (p-value = 0.02) at 6-months of follow-up. Frailty status, when assessed through FTS-5, improved in the intervention group at 3 (p-value = 0.004) and 6 months (p-value = 0.047), while when the Frailty Phenotype Criteria were used, benefits were shown at 3 months of follow-up (p-value = 0.03), but not at 6 months.

Conclusions: The FACET technological ecosystem helps in the early identification of changes in the functional status of prefrail and frail older persons, facilitating prompt clinical interventions thereby improving health outcomes in terms of frailty and functional status, thus potentially preventing disability and dependency. Clinical Trial: NCT03707145

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TITLE

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ABSTRACT

Background: Frailty represents a state of susceptibility to stressors and constitutes a dynamic process. Untreated, this state can progress to disability. Hence, timely detection of alterations in patients' frailty status is imperative to institute prompt interventions and impede progression. With this aim, the FACET technological ecosystem has been developed to provide clinically gathered data from the home to a medical team for early intervention.
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Conclusion: The FACET technological ecosystem helps in the early identification of changes in the functional status of prefrail and frail older persons, facilitating prompt clinical interventions thereby improving health outcomes in terms of frailty and functional status, thus potentially preventing disability and dependency.

TRIAL REGISTRATION: ClinicalTrials.gov NCT03707145.
KEYWORDS: frailty; dependency; functional status; elderly; new technologies; sensor; monitoring system; new technologies; information and communication technologies.

INTRODUCTION

Functional status is one of the best indicators of health condition and predicts poor outcomes in older people better than morbidity [1]. In the pathway leading from robustness to disability, frailty is a dynamic process and transitions that occur in the state of frailty happen bidirectionally: from better to worse states on the spectrum of frailty as well as towards disability [2]. Life expectancy has increased in recent decades [3], leading to an increase in the older population which in turn leads to an increase in the number of frail people. Therefore, prevention and treatment of frailty has generated great interest since it represents a challenge for the health systems [4]. Several studies have shown that multimodal interventions, i.e. those targeting multiple factors, are effective both in primary (prevent or delay the debut of frailty) and secondary prevention (treating the syndrome when it has appeared with the aim of reversing it as much as possible) of frailty, particularly in older individuals with multimorbidity and high healthcare utilization [5][6].
The current medical practice to assess, treat and monitor frailty is carried out through periodic visits of the patient to healthcare settings. Between these visits we have no information about the changing status of the condition, the adherence to treatment and/or the response to it. In recent years, there has been a digital transformation in health care models and these new technologies could provide aids to measure, monitor and treat frailty in older population to prevent health adverse events. Different studies have been carried out within the framework of information and communication technologies (ICTs) and frailty treatment and prevention, but the results obtained are no conclusive given that technologies used are very different, and results are very diverse [7][8].
With this approach in mind, we developed the FACET technological ecosystem, with the aim of improving the effectiveness in the management of frail patients. A technological ecosystem refers to a complex network of interrelated technologies, services, and stakeholders that interact and depend on each other to create a unified and functional environment. The system automatically collects information with high predictive power for adverse events at home. This information comprises speed, power in the lower limbs and involuntary weight loss. This valuable information is complemented with questionnaires to assess nutritional and other data about functional status which are uploaded to the platform. Data are provided to the geriatric team through FACET technological ecosystem.
This research work aims to evaluate the impact of the FACET technological ecosystem when supporting a comprehensive geriatric intervention and follow-up. To do so, a randomized pilot study has been designed to assess whether the information provided by the remote sensors help early detection of functional changes promoting adjusted multimodal intervention in prefrail and frail older persons compared to usual care during a 6-months period.

METHODS

TRIAL DESIGN

This is a multicentre, randomized, simple blind intervention study, with a duration of 11 months (5 months for recruitment, and 6 for intervention). The study was conducted from August 2018 to June 2019, in a geriatric outpatient clinic in two Spanish hospitals (Getafe University Hospital and Albacete University Hospital). The study was registered in clinical trial gov (NCT03707145).

PARTICIPANTS AND RANDOMIZATION

Participants

Participants were recruited in person and by telephone from several settings including the geriatric outpatient clinic, Acute Care Unit (after discharge) and from Primary Care outpatient clinics. Initially, a pre-screening interview was carried out in all of them in outpatient geriatric facility to identify potentially eligible patient who meet the following inclusion criteria:

- Age ≥ 70 years old.
- Living at home.
- Having a caregiver or supervision at home.
- Barthel index ≥ 90.
- Having, at least, 4 comorbidities
- Prefrail older adults: Meet 1 or 2 Fried Frailty Phenotype Criteria.
- Frail older adults: Meet 3-, 4 or 5 Fried Frailty Phenotype Criteria.

The exclusion criteria were:

- Inadequate home infrastructure to host the required technology.
- Inability to understand how to use the FACET system.
- Illness that impedes carrying out the prescribed therapy and/or the follow-up:
    - Acute myocardial infarction in the last 3 months.
    - Unstable cardiovascular disease.
    - Terminal disease (<12 months of life expectancy).
    - Other pathologies involving clinical instability.
- Alcohol/drugs abuse.
- Living with a participant in the trial
- Participation in other interventional clinical studies at the same time.

Finally, to determine if a participant can or cannot understand and use the FACET system, the following procedure will be carried out:

1. Provide indications on how to react to a reminder to perform an action through a mobile device of identical conditions to the one that will be used during the experimentation.
2. Provide indications on how to fill out a test with the mobile device.
3. Generation of a reminder to fill out a test different from the previously shown.

If the potential participant reacts to the alarm and completes the test by him/herself, he/she is considered a suitable candidate.
After verifying that the participants meet the eligibility criteria, the informed consent was signed and

then they were randomized to the intervention or control group.

Settings and locations where the data were collected

Recruitment, assessment, follow-up, and treatment was carried out in parallel in 2 institutions: Getafe University Hospital and Albacete University Hospital. Researchers in charge of doing the intervention or collecting the data along the follow-up were different. While information gathered by the FACET technological ecosystem were revised every week by a non-blind geriatrician, who after reviewing it designed and carried out the different needed interventions during the development of the study in the intervention group, data about the outcomes were collected through face-to-face interviews by another geriatrician, who was blinded regarding the branch where the participant had been randomly allocated every 3 months.

OUTCOMES

The primary outcomes of this study were:

1. To assess whether the FACET monitoring system prevents the worsening of frailty status according to the FTS-5 (Appendix 2; Table 1) and the Fried Frailty Phenotype Criteria (Appendix 2; Table 2) at 3 and 6 months
2. To assess whether the FACET monitoring system improves frailty status according to the FTS-5 and the Fried Frailty Phenotype Criteria at 3 and 6 months

The outcomes were assessed through the following criteria: frailty worsening and improvement.

Frailty worsening

The worsening in frailty status was evaluated according to two different criteria: 1) Changes in the score in the FTS-5 (worsening of 2,5 points or more)[9] and worsening by 1 criterion according to Fried Frailty Phenotype Criteria[10] and 2) by analysing transitions from non-frail to frail according to the FTS-5 [11] and from pre-frail to frail when Fried Frailty Phenotype Criteria were used[12]. Measurements were done at baseline, at 3 months, and at 6 months of follow-up.

Frailty improvement

Similarly, improvements in frailty were quantified according to two set of criteria: 1) Within the FTS-5, based on an improvement of 2,5 points or more[9] and decreases by at least 1 criterion of the Fried Frailty Phenotype Criteria[10] and 2) analysing transitions from frail to non-frail according to the FTS-5 [11] and either from frail to prefrail - robust or from prefrail to robust, according to Fried Frailty Phenotype Criteria [12].

The secondary objectives are:

- Changes in quality of life using EURO-QL-5D-5L at the initial visit, at 3 months, and after 6 months of follow-up.
- Changes in the use of health resources assessed by open questions about number of visits to the emergency room, nursing, primary care physician, primary care, number of falls and hospital admissions in the last 6 months. These data are collected at the initial visit and after 6 months of follow-up.

HYPOTHESIS

The combination of ICT (Information and Communication Technologies) improves the monitoring of the patients at home with an impact on the frailty status**.**

VARIABLES

Data were collected from participants during face-to-face visits in outpatient clinics, at baseline, 3 and 6 months, except cognitive test that were assessed at baseline and at 6 months. Data collected were the following:

1. Demographic data.
2. Comorbidities
3. Medication.
4. Barthel index [13]
5. Frail Phenotype Criteria [12]
6. Frailty Trait Scale 5 [11]
7. Gait speed in 6 meters [14]
8. Mini Mental Status Examination (MMSE) [15].
9. EuroQL-5D-5L [16]
10. Use of health resources in the last 6 months: number of emergency visits, number of hospital admissions, number of visits to primary care physician, number of visits to nursing staff, number of visits to specialist physician, and number of falls.

TECHNOLOGICAL ECOSYSTEM DESCRIPTION

Overview of the FACET monitoring system

FACET monitoring system is a technological ecosystem developed jointly by Getafe University Hospital and Universidad Politécnica of Madrid that lies on the technological substrate of an EU-funded (EIT-Health) research and innovation project: FACET. This project produced a mature and low-cost home monitoring system that aims at preventing functional decline among prefrail and frail older persons, by detecting early functional changes, and generating alerts to promote early interventions to prevent potential adverse events that may lead to disability and dependency. Furthermore, the FACET technological ecosystem provides a means to interconnect the geriatric care team with older persons (see Figure 1).
It is important to remark that the technology under study was fully developed following a co-creation approach [17][18], integrating knowledge and experience from all relevant actors in the process: older persons, healthcare professionals, informal caregivers and technology experts.

FACET monitoring system

FACET technology has two different components (Figure 1):

- Home monitoring subsystem to be used by patients:
    - Mobile application for older persons (figure 2), which offer the following functionalities: continuous frailty follow-up using a home monitoring kit that produces information (gait speed, power in the lower limbs, involuntary weight loss) that is later processed to trigger potential deterioration alerts[19][20]; access to a customized therapeutic plan multicomponent intervention provided by the non-blind geriatrician (medical treatment, VIVIFRAIL physical activity program[21] and nutritional recommendations); retrieving their own evolution; communication with geriatrician via asynchronous channels; notifications on pertinent alarms related to health to activate early interventions, with the goal of preventing disability; reminders to perform the tests that must be carried out at home. The participants in the intervention group accessed to the mobile application through a tablet with 4G connection, provided by the study.

- Monitoring system: the interaction with the home monitoring subsystem is handled by a mobile application that acts as a guiding element to the older person, as a data concentrator (Bluetooth connection with the monitoring kit; (see Figure 1), and as data input point, not only enabling the older adult using the sensors but also completing a set of questionnaires to enrich the information handled by the clinical professionals. The home monitoring kit has been designed to measure variables with high predictive value for adverse events. This kit consists in a gait-speed sensor (figure 3) [20], a sensor to indirectly (through the chair stand test) measure power in the lower limbs (figure 4) [19], and a wireless commercial weight scale to measure involuntary weight loss. This information was enriched to build a short comprehensive geriatric assessment thought different questionnaires which were tailored to language appropriate for the study's target population. The questionnaires that patients complete through the monitoring system is based on the Fried Frailty Phenotype criteria [12], Mini Nutritional Assessment (MNA)[22] Barthel Index[23].

Information collected by this home monitoring kit is processed to trigger potential deterioration alarms.

- Web interfaces for the professionals: it provides the essential infrastructure to offer functionalities to healthcare professionals. These functionalities include storing and accessing clinical information, asynchronous messaging between patients and geriatrician team, displaying alarms based on patient monitoring results, tracking patient's clinical progress (questionnaires, functional test, etc.), as well as prescribing and modifying treatments.

SAMPLE SIZE

There are no similar studies allowing for the a priori estimation of the necessary sample size. Therefore, an initial recruitment target of 90 subjects is set based on the following criteria:

- There are 2 main groups of interest: frail and pre-frail individuals.
- Based on commonly used standards, the recruitment goal is set at 20 subjects per group of interest, totalling 40 subjects for the control group and 40 for the intervention group.
- Assuming a 10-15% loss from the above estimation, the target sample size is established at 90 participants (N = 90).

RANDOMIZATION

For the participants allocation into either the control or the intervention group, a stratified randomization by age (70-85, >85), sex (male, female), diagnosis (frail and prefrail among Fried Frailty Phenotype Criteria) and educational level (higher education, illiterate, others) was carried out to ensure the 2 research arms are properly balanced.

Participants were allocated using the MINIM tool [24] configured according to the study needs. Randomization was performed by the team members not directly involved in the development of the clinical trial.

A recruitment target of 90 participants was established. 44 participants were allocated in control group and 46 in intervention group.

Three professional roles were involved in the study:

- Non-blind geriatricians: check and verify participant's eligibility based on the inclusion and exclusion criteria. Explain the study details and obtain informed consent before randomization. Monitor progress through the FACET system and adjust the treatment as needed along the study.

- Blind geriatricians: they participated in the pre-randomization tasks of the study. They did not received information about the arm to which the patient was randomly allocated. They also made the participant's evaluations at the baseline visit, month 3 and month 6. These researchers did not have access to the data from FACET monitoring system.
- Biomedical engineer: training sessions with the participants on the use of the FACET monitoring system. Installation of technology at home. Resolution of technical problems during the development of the study.

INTERVENTIONS

After signing the inform consent, the participants were allocated into a control or intervention group. Control group (n=44) received usual geriatric care through the classical ways of providing it (comprehensive geriatric assessment, adjustment of polypharmacy, physical, cognitive, and nutritional prescription done face-to-face in classical patients visits). Participants in the intervention group (n=46) received the usual health care by a geriatric team but supported by the information provided by the FACET monitoring system.
Participants were assessed to collect the variables previously described at baseline and after 3 and 6 months of follow-up. After the baseline evaluation, a treatment plan was designed with the following core components: medication adjustment; prescription of physical exercise based on the VIVIFRAIL guide [21]; and dietary recommendations. In the intervention group, the participants were periodically and remotely supervised by their non-blinded geriatrician, who scheduled the questionnaires and tests that the participants must carry out at home to monitor the evolution. Frail Scale, Chair Stand Test, Gait Speed (2.4 meters), and weight were performed once weekly; Barthel Index and FAQ once every 2 weeks and MNA-SF once monthly. These sets of information were captured by the system and stored in the project-dedicated server. The system provides alerts to the clinician (non-blind geriatrician) when pre-established changes were detected.
Non-blind geriatrician checked the platform daily to saw if any alarms had been generated. So, in case that an impairment is detected, the geriatrician would call by phone to check the patient's health status and assess them. The non-blind geriatrician, after this phone call could provide an appointment to attend the patient face-to face if needed. When clinically indicated, he/she made changes in the treatment.
Moreover, the participants and the non-blind researcher could contact by a basic asynchronous communication module along the study.
Those in the control group followed the usual guidelines without technological monitoring.

TECHNOLOGICAL REVISIONS AND UPDATING

The technological solution was frozen during the intervention, which only fixed malfunctions without interfering with the functionalities and services provided.

STATISTICAL ANALYSIS

Statistical analysis was performed by an intention to treat basis.
Summary statistics were presented as means (standard deviation –std-) and N (proportions). Mann-Whitney and Chi-square tests were performed to verify the hypothesis of the randomization scheme.
To assess both main and secondary objectives, we compared both interventions (with and without technology) using multivariate linear regression models for continuous response, multivariate logistic models for dichotomous response (improvement and worsening events) and Poisson models for count responses (i.e. visits to the doctor). The analysis was adjusted for basal functional status (FTS-5) and gender. All the analysis were performed using R for windows 4.1.2. Statistical significance was set at $p < 0,05$.

ETHICAL CONSIDERATIONS

The study followed the principles of the Declaration of Helsinki and was approved by the Getafe Hospital and Albacete Hospital Clinical Research Ethics Committees. The study was approved by the Getafe Hospital Ethics Committee (PY: 17/85).

All participants provided written informed consent before-screening (Appendix 1. Informed Consent).

Participants' data were anonymised, and the data correspondence was stored in a secure digital file supervised by a study engineer.

There was no financial compensation.

RESULTS

RECRUITMENT

Of the 281 individuals who were initially evaluated, 191 were excluded by not meeting inclusion criteria (N=133), refusing to participate in the study (N=36), and for other reasons (N=22). Recruitment ceased when 90 participants were involved. Randomization resulted in the allocation of 44 participants into the control group, and 46 into the intervention group. Out of the whole sample of 90 subjects. In the third month of follow-up, 3 participants from de control group refused to continue in the study and 7 in the intervention group. In the follow-up at month 6, 2 participants from the intervention group dropped out. So, from the original sample, 41 participants from the control group and 37 from the intervention group completed the full study (figure 5. CONSORT diagram).

BASELINE DATA

The baseline characteristics of the participants are summarized in Table 1. Both groups exhibited similar baseline traits. The mean age of our study population was 82.33 (5.91) years. The majority were women (72.22%), had limited education (either no education or only primary studies), and did not use technology daily.

Participants in both groups showed independency in basic activities of daily living, with a mean Barthel Index 94.11 (3.72). Participants met a mean of 2.73 (0.86) criteria and 50% were categorized as frail and 50% as prefrail. The mean score of FTS-5 was 22.89 (6.14).

Upon reviewing the Charlson index, it becomes evident that our patients exhibited high levels of comorbidity. Additionally, the recruited patients were characterized by polypharmacy. Regarding functional status, gait speed, SPPB, and test up and go indicated mild levels of physical impairment. Mean cognitive status values indicated very mild cognitive impairment.

No significant differences were observed between the two groups, confirming the adequacy of the randomization process.

Table 1. Overall Group Description.

	TOTAL	**INTERVENTION GROUP**	**CONTROL GROUP**	**p**
N	90	46 (51.11%)	44 (48.89%)	
AGE[a]	82.33 (5.91)	82.11 (5.42)	82.56 (6.43)	.77
GENDER = MALE[a]	25 (27.78)	14 (30.43)	11 (25)	.56
STUDIES[a]				.14
No education	32 (35.96)	20 (43.48)	12 (27.91)	
Primary education	43 (48.31)	20 (43.48)	23 (53.49)	
Secondary education	11 (12.36)	5 (10.87)	6 (13.95)	

Tertiary education	3 (3.37)	1 (2.17)	2 (4.65)	
EXPERIENCE WITH TECHNOLOGY[a]				.32
Never	56 (62.92)	30 (65.22)	26 (60.47)	
1-2 times	5 (5.62)	4 (8.70)	1 (2.33)	
Occasional use	6 (6.74)	3 (6.52)	3 (6.98)	
Dairy use	22 (24.72)	9 (19.57)	13 (30.23)	
CHARLSON INDEX[b]	5.43 (1.83)	5.64 (1.93)	5.17 (1.69)	.308
NUMBER OF DRUGS[b]	9.44 (3.74)	9.91 (3.91)	8.95 (3.58)	.404
MMSE[b]	26.81 (3.04)	26.98 (2.68)	26.64 (3.39)	.928
MNA[b]	24.63 (3.73)	24.49 (3.82)	24.78 (3.66)	.740
BARTHEL INDEX[b]	94.11 (3.72)	94.24 (3.94)	93.98 (3.51)	.811
SPPB[b]	7.21 (2.54)	7.41 (2.36)	7.0 (2.72)	.464
GAIT SPEED 6m[b]	0.71 (0.22)	0.72 (0.25)	0.69 (0.2)	.923
FRAILTY PHENOTYPE CRITERIA				
Mean number of criteria[b]	2.73 (0.86)	2.74 (0.80)	2.73 (0.92)	.837
Prefrail[a]	45 (50)	22 (47.83)	23 (52.27)	.673
Frail[a]	45 (50)	24 (52.17)	21 (47.73)	
FTS 5				
Mean score[b]	22.89 (6.14)	23.40 (6.56)	22.38 (5.72)	.640
Frail[a]	27 (30.68)	14 (31.82)	13 (29.55)	.817
Non-frail[a]	63 (69.32)	32 (68.18)	31 (71.45)	
EUROQoL[b]	56.07 (25.3)	54.15 (24.78)	58.07 (25.92)	.361

[a]*%.* [b] *(mean (std))*

PRIMARY OUTCOMES AND ESTIMATION

Frailty worsening

A) Changes in FTS-5 score and worsening of 1 criterion in the Fried Frailty Phenotype Criteria: when we compared the intervention and control group along the time through changes in the FTS-5, we observed a 77% reduction in the risk of deterioration at the limits of statistical significance (OR=0.23, 95% IC= 0.05-1.09; *P*=.06) at 3 months in the intervention group that reached the statistical significance at 6 months of follow-up, with a 74% reduction in the risk of deterioration (OR=0.26, 95% IC = 0.07 – 0.98; *P*=.04) (Table 2).

When analysing data based on a 1-point worsening according to the Fried Frailty Phenotype Criteria, the results showed that the intervention group resulted in a 92% lower likelihood of worsening compared to the control group at 6 months of follow-up (OR=0.08, 95% CI=0.01-0.67; *P*=.02) (Table 2). As there were not events at three months in any of the two groups it was not possible to assess the effect.

Table 2: Frailty worsening assessed by FTS-5 (worsening of 2.5 point) and Changes in 1 point in the Fried Frailty Phenotype Criteria.

	P[a]	OR[b]	LL[c]	UL[d]
FTS-5				
M0-M3	.06	0.23	0.05	1.09
M0-M6	.04	0.26	0.07	0.98
Fried Frailty Criteria				
M0-M3	NA[e]	None[f]	None[f]	None[f]
M0-M6	.02	0.08	0.01	0.67

A: P-VALUE. B: ODDS-RATIO. C: LOWER-LIMIT. D: UPPER-LIMIT. E: NA=NOT AVAILABLE. F: NONE=NONE OF THE PARTICIPANTS WORSEN THEIR FRAILTY STATUS (FRIED CRITERIA) AT 3 MONTHS OF FOLLOW-UP.

B) Transitions from non-frail to frail according to the FTS-5 and from pre-frail to frail by Fried Frailty Phenotype Criteria: we did not find significant changes in frailty transitions at either 3 months or 6 months, on either of the two scales (see table 3)

Table 3. Transitions from non-frail to frail by FTS-5 and transition from pre-fral to frail by Fried Frailty Phenotype Criteria.

	P[a]	OR[b]	LL[c]	UL[d]
FTS-5				
M0-M3	.27	0.52	0.16	1.66
M0-M6	.64	0.76	0.24	2.42
Fried Frailty Criteria				
M0-M3	NA[e]	None[f]	None[f]	None[f]
M0-M6	.52	0.43	0.03	5.74

A: P-VALUE. B: ODDS-RATIO. C: LOWER-LIMIT. D: UPPER-LIMIT. E: NA=NOT AVAILABLE. F: NONE=NONE OF THE PARTICIPANTS WORSEN THEIR FRAILTY STATUS (FRIED CRITERIA) AT 3 MONTHS OF FOLLOW-UP.

Frailty improvement

A) There was a higher likelihood of improvement in frailty status through FTS-5 occurring in the intervention group compared to the control group at three months, with an odds ratio of 4.16 (95% CI = 1.57 – 11.03; *P*=.004). The benefits remain at 6 months, with an odds ratio of 2.63 (95% CI = 1.004 – 6.90; *P*=.047).

According to Fried Frailty Phenotype Criteria there was an improvement in the intervention group compared to the control group, with an odds ratio of 4.50 (95% CI = 1.17 – 17.38; *P*=.03) at 3 months of follow-up. The improvement was not observed at the 6-month of follow-up (see table 4).

Table 4. Frailty improvement assessed by changes in 2,5 points in FTS-5 and changes in 1 criterion by Fried Frailty Phenotype Criteria.

	P[a]	OR[b]	LL[c]	UL[d]
FTS-5				
M0-M3	.004	4.16	1.57	11.03
M0-M6	.047	2.63	1.004	6.90
Fried Frailty Criteria				
M0-M3	.03	4.50	1.17	17.38
M0-M6	.63	1.37	0.37	5.03

A: P-VALUE. B: ODDS-RATIO. C: LOWER-LIMIT. D: UPPER-LIMIT.

B) Transitions from frail to non-frail according to the FTS-5 and from pre-frail to robust or from frail

to pre-frail or robust by Fried Frailty Phenotype Criteria: we did not observe statistically significant results by FTS-5 at 3 or 6-month of follow-up. However, when we analysed transitions by Fried Frailty Phenotype Criteria, the results indicated a marginal higher likelihood of improvement in frailty status occurring in the intervention group compared to the control group, with an odds ratio of 3.10 (95% CI = 1.01 – 9.54; *P*=.049). These benefits did not persist at 6 months, with an odds ratio of 1.50 (95% CI = 0.54 – 4.13; *P*=.44) (see table 5).

Table. 5. Transitions from frail to non-frail by FTS-5. Transitions from pre-frail to robust, or from frail to pre-frail or robust by Fried Frailty Phenotype Criteria. .

	***P*[a]**	**OR[b]**	**LL[c]**	**UL[d]**
FTS-5				
M0-M3	.27	1.93	0.60	6.21
M0-M6	.64	1.32	0.41	4.19
Fried Frailty Criteria				
M0-M3	.049	3.10	1.01	9.54
M0-M6	.44	1.50	0.54	4.13

A: P-VALUE. B: ODDS-RATIO. C: LOWER-LIMIT. D: UPPER-LIMIT.

These transitions are shown in more detail in tables 6 (FTS-5) and 7 (Fried Frailty Criteria).

Table. 6. Frailty transitions by FTS-5 (%).

	Worsening	**No changes**	**Improving**
FTS-5			
M0-M3			
Control	19.51	46.34	34.15
Intervention	5.13	38.46	56.41
M0-M6			
Control	21.95	31.71	46.34
Intervention	8.11	27.03	64.86

Table. 7. Frailty transitions by the Fried Frailty Phenotype Criteria (%).

Fried Frailty Criteria				
M0-M3				
		Robust	**Prefrail**	**Frail**
Robust	Control	0	0	0
	Intervention	0	0	0
Prefrail	Control	9.9	90.91	0
	Intervention	11.11	88.89	0
Frail	Control	0	36.84	63.16
	Intervention	4.76	66.67	28.57
M0-M6				
		Robust	**Prefrail**	**Frail**
Robust	Control	0	0	0
	Intervention	0	0	0
Prefrail	Control	13.64	77.27	9.09
	Intervention	21.05	73.68	5.26
Frail	Control	0	47.37	52.63
	Intervention	5.56	50	44.44

In this same regard, as a whole the mean improvement in the Fried´s criteria was marginally higher in the intervention group at 3 (0.34; 95% CI = -0.05 – 0.74; *P*=.09) and 6 months (0.42; 95% CI = -0.02 – 0.87; *P*=.06) while it reached statistical significance when FTS-5 was used, both at 3 (2.85; 95% CI = 0.92 – 4.77; *P*=.005) and 6 months (2.10; 95% CI = 0.07 – 4.14; *P*=.04) (Appendix 2, Table 3).

SECONDARY OUTCOMES

We did not find significant changes in any of the secondary outcome, except for falls. We did not detect changes in the visits to the Emergency Room, hospitalizations, visits to Primary Care physician and nurse, number of falls nor Quality of Life (Appendix 2. Table 4).

DISCUSSION

The main finding of our study is that the use of the FACET technological ecosystem, used over a 6-month period, prevents the impairment and improves the frailty status disregarding the method used to assess it and avoids the progression of frailty according to the FTS-5 scale. Additionally, the data suggests that this benefit is obtained quite early, and it is maintained after six months of follow-up, although with a tendency to moderate its impact.

It is worthy to mention that FACET per se does not provide any intervention (changes in physical exercise, nutrition, drugs...), which is decided by the geriatrician, but only makes a monitoring of functional variables. This means that a tight monitoring which allows an early detection of functional deterioration which generates alerts to the geriatrician is a relevant component to obtain benefits in this pre-frail and frail population, no matter the type of intervention provided. This finding reinforces the concept of a low functional reserve classically linked to the presence of frailty [6], a fact that highlight the need of an intervention as earlier as possible to avoid further deteriorations that are quickly developed in the absence of any intervention.

Although the data are quiet consistent no matter the frailty scale used, they are sounder when we assessed participants through the FTS-5. It is crucial to note that the FTS-5 assesses a continuous

multisystemic gradient, which makes it a more sensitive scale to changes and enabling better detection of biological dysfunction, ranging from a state of robustness to the most vulnerable individuals [25][11]. It exhibits a heightened sensitive in identifying even the slightest alterations in frailty status, which could justify the results obtained. Another explanation for these mild differences stems from the findings that these two scales (FTS-5 and Fried Frailty Phenotype) show a low agreement as it has been recently reported in a study which evaluated the different tools that assess frailty [26], raising the possibility that they capture different dimensions of frailty [27][28]. In this regard, some researchers postulate the existence of different types of frailty [29].

COMPARISON WITH PRIOR WORKS

All previous studies conducted in this field differ from ours in their inability to integrate information acquired through novel technologies with comprehensive geriatric assessments, aiming to enhance the evaluation and intervention processes for frailty.

Numerous clinical studies have been developed to enhance frailty diagnosis and treatment through information and communication technologies. However, results from these studies vary significantly, reflecting a wide array of devices employed for these purposes. This diversity complicates drawing definitive conclusions about the practical use and implementation of new technologies in clinical settings [8].

Most studies assess frailty based on the Frailty Phenotype, while others employ the Frail Index. A similar study to ours was conducted in the United States by Upatising B et al. [30], involving 205 older adults (100 men) with an average age of 80.4 years, recruited from primary and community care. The study aimed to assess whether 12-month home monitoring could prevent frailty and mortality in patients with clinical issues. The devices utilized included a remote surveillance system, a health guide placed in the home, and other peripheral equipment connected to the healthcare system. Parameters such as heart rate, blood pressure, oxygen saturation, glucose level, and weight were monitored at home. Results showed that home monitoring did not reduce functional decline, as measured by frailty and mortality rates, among older adults. Moreover, the home monitoring system itself did not induce changes in patients' functional status. Instead, the study indicated a need for reevaluating the organizational model. A major limitation of that study was the absence of a clinical intervention, as they only detect status which did not promote an intervention, while in our study the detection of an impairment promoted an alert motivating a contact between the clinician and the patient. This fact may explain at least partially the differences in our findings. In fact, simple monitoring should not be expected to produce any effect, without intervention.

Another randomized clinical trial conducted by Geraedts Hae et al. [31], investigated whether frail older individuals, using a portable physical activity sensor, showed increased adherence and efficacy in a personally tailored home-based physical activity program. Subsequently, feedback was provided, including videos demonstrating the exercises. The study concluded that patients using these sensors exhibited superior mobility outcomes compared to the control group.

STRENGTHS AND LIMITATIONS

The study exhibits both strengths and limitations. One of its primary strengths lies in its internal validity, given its status as a randomized controlled trial. The control and intervention groups were meticulously balanced and comparable at the baseline, enhancing the study's credibility. Moreover, this study stands as the first of its kind to assess the effectiveness of an intervention integrating a home monitoring system with a classically provided comprehensive geriatric assessment and

intervention. This assessment evaluated cognitive, affective, and physical domains, nutritional status, and social circumstances of older individuals, while also attempting to reshape the existing organizational model. The mean age of the participants is high, which provides the study with validity when implementing the results in clinical practice. Another strength lies in the co-creation of the technology with older individuals, ensuring high adherence to the FACET technological ecosystem [18].

However, the study is not without its limitations. Firstly, there were more dropouts in the intervention group, potentially attributed to the low digital literacy of the participants, who might have felt overwhelmed by the technology. Another limitation stemmed from the challenge of maintaining blinding throughout the study. Some participants revealed their research group affiliation during evaluation visits, although the researcher remained unaware of the previous assessments.

CONCLUSION

In conclusion, the findings obtained through this research work demonstrate that the FACET technological ecosystem effectively helps in the early identification of changes in the functional status of prefrail and frail older persons, facilitating prompt clinical interventions thereby improving health outcomes in terms of frailty and functional status, which may lead to disability and dependency.

As a result, we may conclude that the integration information and communication technologies such the one used in this study has proven to be an asset in routine clinical practice. Nevertheless, further studies are warranted to advance our understanding in this area.

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DATA AVAILABILITY

Restrictions apply to the availability of the data used in this study due to the private nature of the health information contained. These data are not publicly available but are available from the authors upon reasonable request and with permission of Getafe University Hospital.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTION

LR-M generated the original idea and coordinated the team. RP-R, PM-S, and EV-M conceptualized and materialized the technological approach. MV-A, RP-R, PM-S, MO-B, and LR-M designed the trial. RP-R led and supervised the correct execution of the experiment, with support from PM-S, MV-A, MO-B, PA-S and EV-M. JC performed the statistical analysis. MV-A, MO-B and LR-M

analysed the clinical results. All authors participated in writing the manuscript.

ABBREVIATIONS

CI: confidence interval
CST: chair stand test
EIT-Health: European Institute of innovation and technology
EU-Funded: Europe Union-Funded
FTS-5: Frailty Trait Scale-5
ICTs: information and communication technologies
MMSE: mini mental state examination
MNA: mini nutritional assessment
MNA-SF: mini nutritional assessment-short form
SPPB: short physical performance battery

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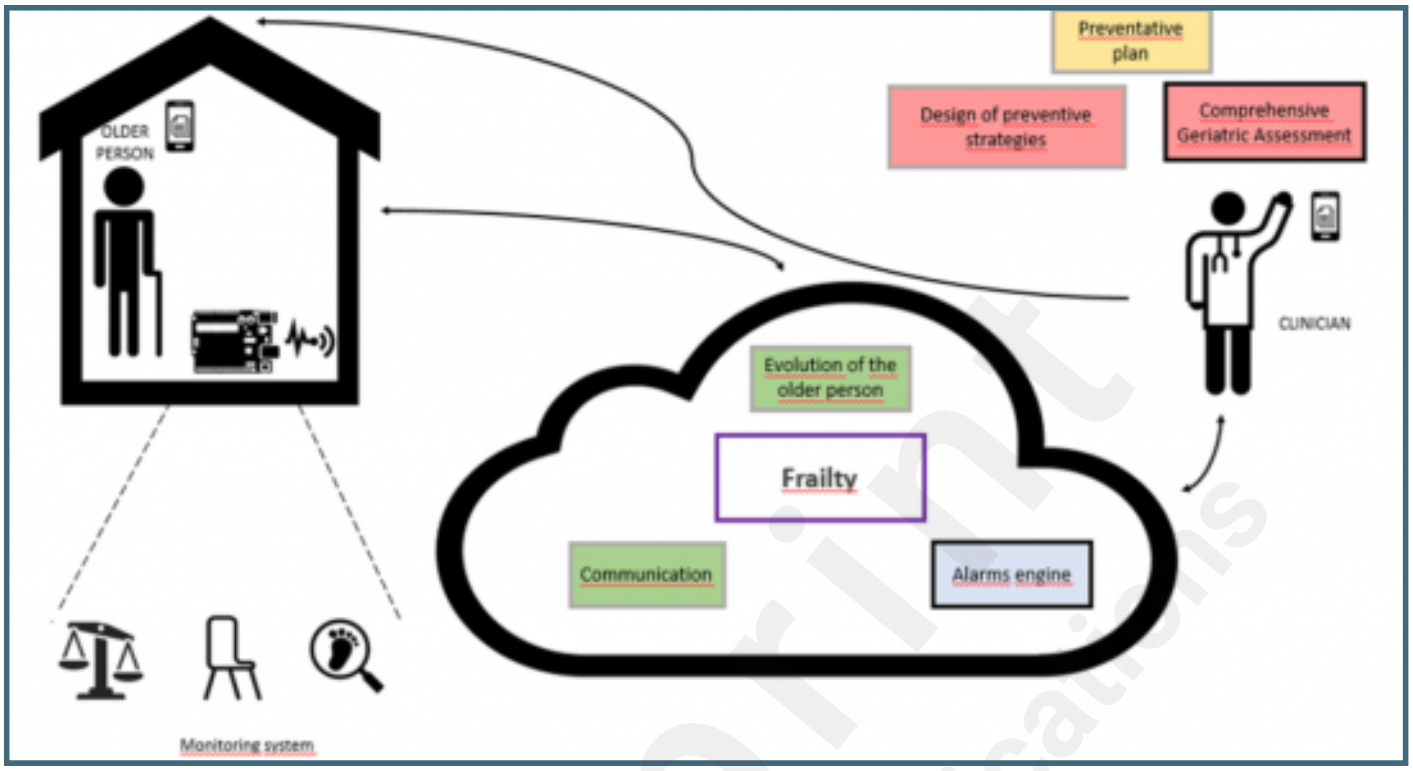
Supplementary Files

Figures

The FACET system: components and users.

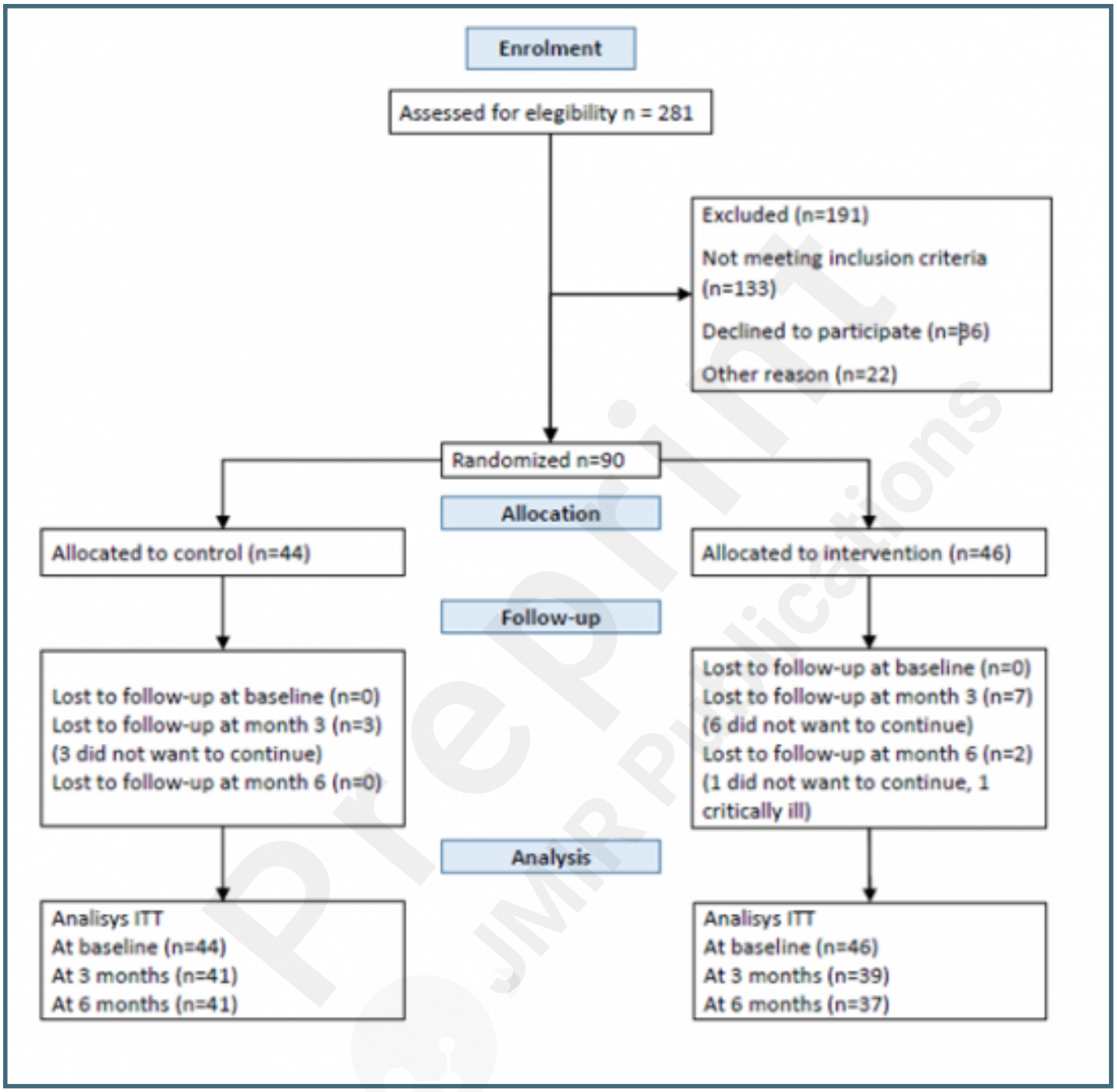


Mobile application.

Gait speed sensor.

Lower limbs power sensor.

CONSORT flow-chart diagram.



Multimedia Appendixes

Informed consent.
URL: http://asset.jmir.pub/assets/edccde6da8f55010d4c31df566ee9060.docx

Additional material.
URL: http://asset.jmir.pub/assets/cc197488a22d00bdb44b0e272e57a7f1.docx