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Importance of Health Policy and Systems Research for Strengthening Rehabilitation in Health Systems: *A Call to Action to Accelerate Progress*

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This editorial is being published almost simultaneously in all journals listed at the end to reach as many readers as possible.

During the last few decades, the field of rehabilitation has experienced substantial development, growth, and acceptance. Rehabilitation addresses the impact of a health condition on a person's everyday life by optimizing their functioning and reducing their experience of disability. Rehabilitation expands the focus of health beyond preventative and curative care to ensure people with a health condition can remain as independent as possible and participate in education, work, and meaningful life roles Organisation [1]. A definition of rehabilitation for research purposes has been recently published Negrini et al. [2]. Scientific and clinical research have generated a body of knowledge that strongly supports the use of many rehabilitation interventions with positive outcomes in various populations and health conditions.

We also have now a better understanding of the growing global need, demand, and recognition of rehabilitation around the world. For example, it has been estimated that 2.41 billion people in the world could benefit from rehabilitation services. This means that at least one in every three persons in the world needs rehabilitation at some point during the course of their disease or injury Cieza et al. [3]. This figure has most likely increased because of the COVID-19 pandemic. The need for rehabilitation increased by 63% between 1990 and 2017 because of the aging population, the increasing prevalence of noncommunicable health conditions, and the shifting epidemiological profile in most countries Cieza et al. [3]. Finally, according to the 2022 global report on health equity for persons with disabilities, approximately 1.3 billion people or 16% of the world's population has moderate to severe levels of disability associated with the underlying health conditions and impairments Organisation [4]. Now more than ever before, it is crucial that rehabilitation is available and accessible to populations globally according to their needs. The important contribution of rehabilitation to the functioning, including social and occupational participation and well-being of populations worldwide, can no longer be denied or delayed. Rehabilitation is critical for the attainment of the United Nations Sustainable Development Goal 3, *Ensure healthy lives and promote well-being for all at all ages* UN [5].

Notwithstanding the foregoing arguments, there continues to be a high unmet need for rehabilitation globally, with some low- and middle-income countries reporting unmet needs up to 50% of those who could benefit from rehabilitation. Rehabilitation services are not accessible to many people around the world Kamenov et al. [6]. Many of those in need do not have access because of the failure, at least partially, to effectively plan for rehabilitation services. Many nations and health systems have not implemented policy measures that recognize rehabilitation as an essential component of universal health coverage Litullo [7], Negrini et al. [8]. Health policy, planning, and decision making for rehabilitation often require more local evidence to adequately plan, finance, implement,and monitor quality rehabilitation services including infrastructure and workforce to make services accessible to those in need Organisation [9].

The field of health policy and systems research (HPSR) seeks to understand and improve how societies organize themselves in achieving collective health goals and how different actors interact in the policy and implementation processes to contribute to policy outcomes Organization [10], for Health Policy and Research [11]. By nature, it is interdisciplinary, a blend of medicine and health sciences, economics, sociology, anthropology, political science, law sciences, public health, and epidemiology that together draw a comprehensive picture of how health systems respond and adapt to health policies, and how health policies can shape—and be shaped by—health systems and the broader determinants of health. The importance of HPSR for rehabilitation has been recently highlighted with robust data that needs to be considered and used by health policy and systems community and leadership Cieza et al. [12]. Health policy and systems research for rehabilitation generates the evidence needed by policy makers to make appropriate decisions and to develop action plans to enhance the capacity of the health system to serve the population in need of rehabilitation services. For example, the evidence generated by HPSR helps (1) establish priorities for rehabilitation service delivery, (2) evaluate outcomes of various rehabilitation interventions in relation to the levels of care in the health system, (3) identify specific benefits to society justifying those decisions, and (4) strengthen health systems to increase access, quality, and provision of health services for rehabilitation Cieza et al. [13]. Supported by the recent resolution on 'Strengthening rehabilitation in health systems' that has been endorsed by the World

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Health Assembly for the first time in the history of the World Health Organization Organisation [14], it is time to leverage HPSR to support societal health goals as they apply to rehabilitation.

In 2022, the World Health Organization Rehabilitation Program established the World Rehabilitation Alliance (WRA) Organisation [15] to strengthen networks and partnerships that advocate for the integration of rehabilitation into health systems. The WRA is a World Health Organization–hosted global network of stakeholders whose mission and mandate are to support the implementation of the Rehabilitation 2030 Initiative Organisation [16] through advocacy activities. The WRA focuses on promoting rehabilitation as an essential health service that is integral to Universal Health Coverage and to the realization of the United Nations Sustainable Development Goal 3. The work of the WRA is divided into the following five workstreams: workforce, primary care, emergencies, external relations, and research. The research workstream is dedicated to the generation and routine use of HPSR evidence for planning and integrating rehabilitation into health systems. The specific objectives of this workstream are to advocate for (1) the demand and utilization of HPSR evidence for rehabilitation, (2) the widespread generation of high-quality HPSR evidence for rehabilitation, and (3) the publication, dissemination, and implementation of HPSR evidence for rehabilitation.

In this context, the coauthors of this editorial on behalf of their respective academic journals express their full support for the WRA mission in general and for the specific objectives of the research workstream. In concrete terms, we commit that our journals, as much as possible, will implement one or more of the following actions: (1) invite researchers in the field of HPSR for rehabilitation to submit their manuscripts to our Journals for peer review and possible publication, (2) create a special journal section, series, or designation dedicated to HPSR for rehabilitation, (3) appoint editorial board members with expertise in HPSR for rehabilitation, and (4) disseminate research articles among funding agencies and policymakers. These actions by our academic journals will help the WRA achieve its goal of strengthening rehabilitation services for all.

Competing interests

Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.

Provenance

This editorial is being published almost simultaneously in all journals listed to reach as many readers as possible.

Acta Fisiatrica; Advances in Rehabilitation Science and Practice; American Journal of Physical Medicine and Rehabilitation; Annals of Geriatric Medicine and Research; Archives of Physical Medicine and Rehabilitation; Australian Occupational Therapy Journal; Brain and Spine; Chiropractic and Manual Therapies; Die Rehabilitation; European Journal of Physical and Rehabilitation Medicine; European Rehabilitation Journal; Foundation University Journal of Rehabilitation Sciences; Frontiers in Rehabilitation Sciences; Journal of Manipulative and Physiological Therapeutics; Journal of Occupational Rehabilitation; Journal of Pakistan Medical Association; Journal of Prosthetics and Orthotics; Journal of Rehabilitation Medicine; Journal of Speech, Language, and Hearing Research; Medicina Riabilitativa; Neuropsychological Rehabilitation; Neurorehabilitation and Neural Repair; Portuguese Journal of Physical and Rehabilitation Medicine; Rehabilitación; Revista Colombiana de Medicina Física y Rehabilitación; Revista Mexicana de Medicina Física y Rehabilitación; Revue Santé Publique; South African Journal of Physiotherapy; The Journal of the International Society of Physical and Rehabilitation Medicine; Turkish Journal of Physical Medicine and Rehabilitation.

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Physiotherapists have a major role in Environmental Health

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Physiotherapists and occupational therapists focus on the overall function of patients rather than just on their disease(s). As rehabilitation professionals, they treat pain, instabilities and disabilities, with the aim of enhancing the participation of patients. They also work with healthy people to avoid or delay the arrival of impairments to the musculoskeletal system. With this global approach, centralised on the physiological reserves of our body, physiotherapy can easily comply with the "One Health" concept.

"One Health" is defined by the Centres for Disease Control and Prevention as a "collaborative, multisectoral, and transdisciplinary approach, working at the local-regional-national and global levels, with the goal of achieving optimal health outcomes recognising the interconnection between people, animals, plants and their shared environment" [1]. Among the key factors of well-being, our environment forms the basis. The shadow of climate change is growing. In just a few years, the concept of environmental health has become widely accepted. Environmental health is a branch of public health, which focuses on the health effects of human interactions with the environment. It is a multidisciplinary field that studies how the environment affects the health and well-being of individuals and populations, and – in a minor part - how the health system contributes to climate change. The term environmental health is broad and includes air pollution, water pollution, hazardous waste, climate change, and other environmental issues.
Environmental health researchers and professionals aim to prevent diseases caused by environmental factors, developing strategies oriented towards two main goals: human health itself (preventing behaviours) and environmental protection (reducing the impact of environmental factors on human health). Indeed, environmental protection is a major key to protecting human health, since a high number of health determinants are dependent on the quality of air, water, soil, food, etc. [2].

With the environmental health concept in mind, we can take into consideration the numerous co-benefits that arise when we plan health and environment protection together [3]. As rehabilitation professional or sports instructors, we can lead this movement, as we understand the mutual benefits of encouraging patients to move or to be active. We can reduce Greenhouse Gas (GG) emissions caused by our displacements by travelling, when possible, by foot or bicycle [4]. Moving actively, we protect ourselves against several diseases (cardiovascular or neurodegenerative, for example) [5, 6, 7]. From an individual point of view, what is positive for one's health is also beneficial for the environment, and conversely. In addition, walking or cycling instead of driving a car also avoids pollution for the local community. Therefore, when we protect ourselves, we also protect humanity.
We can also cite nutrition since physiotherapists also play a role in the promotion of dietary behaviours. Modifying dietary behaviours such as decreasing meat consumption is efficient in reducing GG emissions, thus protecting the environment [8]. In addition, this dietary change could also contribute to reducing the risk of developing several cancers [9].

As health professionals, we must integrate the notion that our health begins by nature's health, as we are nature [10]. In France, the health system is responsible for 8% of the GG emissions [4]. The huge priority given to pharmaceutical solutions (i.e. medication) is probably a key factor. Chemical treatments are often necessary, and we continue to expect further progress to treat certain diseases this way. However, medications are over-consumed worldwide. In this context, rehabilitation professional could help reduce the consumption of Non-steroidal anti-inflammatory drugs (NSAIDs), for example [11]. Although the pharmaceutical industry is responsible for a major part of GG emissions, health professionals should also recognise their collective responsibility in the environmental destruction, and the consequences for their patient's health.

We ask patients to be "active" during their rehabilitation, whereas effort should be an internal motivation for each of us in all stages of life. When we perform tasks actively, we understand how much energy is required to perform each task. Taking stairs for example, instead of using the elevator is the beginning of this change that could improve health and a reduce energy consumption.
Several physiotherapists are aware of this important issue and have formed the Environmental Physiotherapy Association [12]. They empower a network of physiotherapy clinicians, educators, researchers, and students interested in exploring and advancing the field of environmental physiotherapy. It is time for us all to join this kind of dynamic.

Whom better than rehabilitation professional to impulse this paradigm change in our health systems?

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EUROPEAN REHABILITATION JOURNAL | ORIGINAL

Negative influence of a mediatised video on low back pain-related misbeliefs and attitudes in the general population

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ABSTRACT

Background: Low back pain (LBP)-related misbeliefs are a risk factor for chronicity and thereby require further attention. **Objective**: To assess the influence of a mediatised video on LBP-related misbeliefs in the general population and to examine whether these individuals intended to change their behavior to protect their back after viewing the video. **Method:** French-speaking adults within the general population were recruited through advertisements and were asked to complete a self-administered questionnaire, available online between January 2021 to April 2021. The questionnaire asked about socio-demographic information and back pain beliefs (the 10-item Back-PAQ). Participants were then prompted to watch a mediatised video conveying negative messages. Immediately after viewing the video, participants indicated their degree of agreement with the messages conveyed they completed the Back-PAQ a second time and they indicated whether they intended to change their behavior as a result of watching the video. Changes in mean Back-PAQ score after viewing the video and the percentage of participants planning to protect their backs more were investigated. The influence of a history of LBP was also analysed. **Results**: 1338 participants were included. The initial mean Back-PAQ score was high (28.3 (SD 6)) and increased significantly after viewing the video (Cohen d: 0.42), indicating an increase in negative beliefs. This change was greater than the minimum detectable change (6.8) for 11.4% of participants. In total, 55% of respondents reported that they would protect their backs more after watching the video. Pain history did not influence the change in Back-PAQ score post viewing. **Conclusions**: This study demonstrates that a mediatized video which conveys negative messages about LBP reinforces LBP-related misbeliefs and may promote maladaptive behavior in a significant number of individuals. This study also confirms the prevalence of such misbeliefs in the general population and thereby, the necessity for clinicians to explore patients' misbeliefs and their origin.

KEYWORDS: beliefs, fear, knowledge, low back pain, communication.

Introduction

Low back pain (LBP) is one of the most common causes of disability [1] and a socio-economic burden [2]. More than 70% of individuals experience LBP in their lifetime; the number of years of disability due to LBP increased by 54% from 1990 to 2015 [2]. It is now commonly accepted that LBP management strategies should not follow a biomedical model but should instead be based on a bio-psycho-social model, particularly when there is a risk of chronicity or when the disorder is already chronic [3, 4, 5]. Among the "yellow flags", considered as risk factors for the transition to, and maintenance of, chronicity are "LBP-related misbeliefs" [5, 6, 7, 8]. Williams and Thorn defined pain beliefs as "patients' own

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conceptualisations of what pain is and what pain means for them" [9]. They can play an important role in behavioural and emotional responses to musculoskeletal pain [10]. Some pain beliefs can be positive/helpful (e.g. positive expectations) [11, 12] but others are based on inaccurate or incomplete information which are discordant with current scientific knowledge. The importance to consider pain beliefs are highlighted by their aforementioned consequences. LBP-related misbeliefs are common in the general population [13] and have been highlighted in community samples in New Zealand [14], Argentina [15], Norway [16], Switzerland [17] and Belgium [18]. LBP-related misbeliefs can be unhelpful as they can negatively impact pain intensity, disability, use of drugs and health care utilisation [8, 19, 20, 21]. Furthermore, LBP-related misbeliefs can induce catastrophic thoughts and avoidance behaviours [8, 22, 23, 24] e.g., avoidance of spinal flexion to "protect" the back [10]). Indeed, one of the most common beliefs is that the back is fragile and vulnerable and should be protected by limiting certain movements such as bending and lifting [8, 25, 26, 27, 28].

LBP-related misbeliefs may have different origins [8, 10], one of which may be the influence of media. Few studies have evaluated the potential influence of the media on negative beliefs about LBP. A recent video clip of a popular health professional discussing LBP was broadcast in French on social media to promote a high-profile French television program. The clip contained negative messages about LBP that contradicted with current recommendations [29]. As beliefs are modifiable, we used this opportunity to assess the impact of viewing the video clip on LBP-related beliefs within the general public. Our primary objectives were to determine the extent to which viewing the video changed beliefs regarding LBP in the general public and to examine whether participants intended to change their behavior to protect their back as a result of viewing the video. The secondary aim was to compare the impact of the video on beliefs between asymptomatic subjects (with or without a history of LBP) and those with ([sub]acute or chronic) LBP.

We hypothesised that LBP-related misbeliefs would increase after viewing the video clip in most people, regardless of the LBP past history of LBP, and that it might favor spinal protection behaviors.

Method

Study design and setting

A prospective pre-post study in which participants were invited to complete a questionnaire before and after watching a video clip was conducted. The questionnaire was available online on a digital platform (LimeSurvey) between 11/01/2021 to the 03/04/2021. The study protocol was approved by the Ethical committee of the University of Liege on 20/09/2020. All participants were volunteers, were informed about the study and gave their consent for participation.

Participants

To be eligible for participation in the study, participants had to be 18 years old or over, French-speaking and live in Europe (Belgium, France, Luxembourg or Switzerland). Exclusion criteria included visual impairment which prevented individuals from watching the video, not having an internet connection and all graduates from physiotherapy, osteopathy, occupational therapy, medicine (specialised in the management of LBP). Participants who did not complete every section of the questionnaire, those that did not provide consent for participation or who indicated that they had not watched the video were also excluded. A non-probabilistic recruitment method was used: participants were recruited using convenience sampling via mailing lists, flyers posted in numerous public places (e.g., hospitals, mailboxes, bakeries, supermarkets, etc.) and announcements posted on social networks (Facebook and Instagram).

Procedure and measures:

Individuals who wished to participate were invited to go to the LimeSurvey online questionnaire platform to complete the questionnaire using the web link or QR code found on the flyer/announcement. The questionnaire included several sections. It was not possible to go back to the previous section to change previous responses.

Section 1: Consent Once the questionnaire was opened, the respondent had to give consent in order to proceed to the next section.

Section 2: Sociodemographic characteristics: This section collected data of participant's general characteristics (age, gender, level of education, professional status), the presence of LBP in the last 24 hours (and, if present, the duration of the pain) and the individual's history of LBP so that we could classify participants into 4 subgroups: asymptomatic without history of LBP, asymptomatic with history of LBP, (sub)acute LBP (pain for less than 3 months) and chronic LBP (pain for more than 3 months).

Section 3: Pre-video questionnaire (Beliefs relating to LBP): The short version of the French version [30] of the Back-Pain and Attitudes Questionnaire [31] which is comprised of 10 items (statements) rated on a 5-point Likert scale ranging from 1 (false) to 5 (true) was used. The total score (ranging from 10 to 50) was calculated by summing the score for each item (the scores for items 6, 7 and 8 are reversed). Higher scores indicate more negative beliefs. This questionnaire has good reliability and the minimum detectable change (MDC) is 6.8 points [30].

Section 4: Video clip about LBP: The 4.24 minutes video clip used in the present study was broadcast on one of the main French TV channels website and on social networks, in particular on Facebook. It was an extract from a television programme presented by a popular French doctor and a celebrity. The video clip consisted of a doctor discussing everyday movements that he described as harmful to the back and that he strongly advised against performing to avoid putting one's back at risk. He provided seven main messages which can be found in the Tables. At the end of the video, participants were asked to confirm that they had watched the entire video.

Section 5: Post-video questionnaires: Immediately after the viewing, participants completed:

- A custom-made questionnaire designed to examine the degree of agreement with the 7 statements described above using a 5-point Likert scale: "Strongly agree", "Agree", "Undecided", "Disagree", "Strongly disagree". A score of −2, −1, 0, 1 and 2 points was respectively assigned to each response and the total score was calculated (range -14 to 14 points). We found good test-retest reliability for this questionnaire in a preliminary unpublished study (ICC: 0.98).
- The Back-PAQ (post viewing).
- The question: "After watching this video, do you plan to change how you perform your daily activities and will you pay more attention to protecting your back?".

Once the questionnaire was finished, a closing statement was provided in order to reassure participants that their back is a strong structure, and to explain the benefits of movement (even in the presence of back pain) and the potential risks associated with the systematic avoidance of basic movements. This explanation was added so that participation in this study would not be "harmful" to participants.

Statistical analysis

Statistical analyses were performed by a statistician who used JMP Pro 16.0.0 and SAS 9.4 software. Descriptive data were expressed as numbers and percentages for categorical variables, means and standard deviations

Table 1 Sociodemographic characteristics of the 4 subgroups.

	Asymptomatic – no history of LBP	Asymptomatic – with history of LBP	(Sub)acute LBP	Chronic LBP	Total
	n = 290	n = 503	n = 164	n = 381	n = 1338
Sex, n (%)					
Female	176 (60.7)	345 (68.6)	118 (72)	255 (66.9)	894 (66.8)
Male	113 (39)	155 (30.8)	46 (28)	126 (33.1)	440 (32.9)
Other	1 (0.3)	3 (0.6)	0	0	4 (0.3)
Age in years, mean (SD)	29.8 (14.2)	34.3 (15.7)	30.3 (13.0)	38.0 (17.0)	34.0 (15.8)
Level of education, n (%)					
Primary	1 (0.30)	2 (0.4)	1 (0.6)	3 (0.8)	7 (0.50)
Secondary	33 (11.4)	51 (10.1)	28 (17.1)	28 (17.1)	177 (13.2)
Higher education	256 (88.3)	450 (89.5)	135 (82.3)	313 (82.2)	1154 (86.3)
Professional status, n (%)					
Working	111 (38.3)	251 (49.9)	71 (43.3)	199 (52.2)	632 (47.2)
On sick leave	1 (0.30)	6 (1.2)	1 (0.60)	12 (3.1)	20 (1.5)
Unemployed	7 (2.4)	8 (1.6)	1 (0.60)	13 (3.4)	29 (2.2)
Retired	15 (5.2)	33 (6.6)	4 (2.4)	35 (9.2)	87 (6.5)
Student	152 (52.4)	203 (40.3)	84 (51.2)	121(31.8)	560 (41.9)
Other	4 (1.4)	2 (0.40)	3 (2.0)	1 (0.30)	10 (0.70)

LBP: low back pain.

(SDs) for continuous variables, and medians and interquartile ranges (IQRs) for variables with a non-normal distribution. The effect-size (Cohen d) was calculated by dividing the mean difference by the standard deviation. Comparison of the change in Back-PAQ score between the four subgroups (with respect to LBP history) was analyzed using a mixed model with a random subject effect. The Kruskall Wallis test was used to compare change in Back-PAQ score (post value minus pre value) between the 4 subgroups. In case of significance, pairwise between-group comparisons were performed with a non-parametric test with correction for multiplicity (Steel-Dwass method). A McNemar test was used to compare the percentages of participants who chose each response option between pre and post viewing for each item of the Back-PAQ.A p-value < 0.05 was considered statistically significant.

Results

A total of 2194 individuals opened the questionnaire. Of these, 728 did not complete the entire questionnaire, and 123 reported not having watched the video. Therefore, 1338 participants were included in the analyses (Figure 1).

General socio-demographic and LBP-related information

Mean age of the total sample was 33.9 years (Table 1). The majority were female (66.8%), with a high education level (86.2%). Less than half of the sample were professionally active (47.2%) and 41.8% were students. With regards to location, 84.5% lived in Belgium, 15.1% in France, and the few remaining participants lived in the Grand Duchy of Luxembourg or Switzerland. Most respondents (1048/1338, 78.3%) reported currently having or having experienced LBP previously. Of these, 381/1338 (28.5%) and 164/1338 (12.2%) reported having chronic or (sub)acute LBP respectively at the time of the questionnaire; 290/1338 (21.7%) reported no LBP in the last 24 hours and no history of LBP, and 503/1338 (37.6%) reported being currently asymptomatic with a history of LBP.

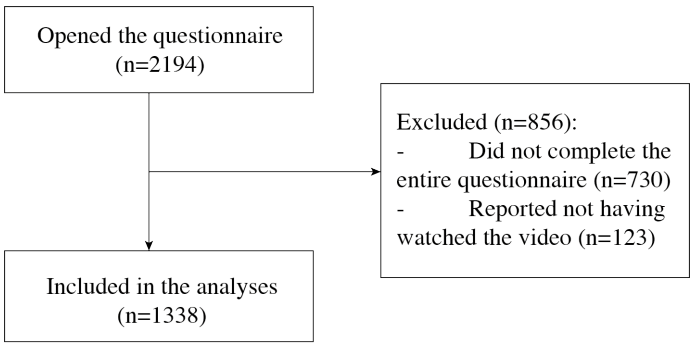

Figure 1 Figure 1: Flow chart of inclusions

Ratings of agreement with the messages in the video clip

Mean total score for the degree of agreement with the 7 messages was −6.9 (SD 6.0). Table 2 shows that at least half individuals (>53%) agreed or strongly agreed with all 7 messages. Agreement with messages 5 ("When picking up an object from the ground, squat down instead of bending forward to avoid hurting your back") and 7 ("Avoid wearing a backpack with only one shoulder strap to avoid hurting your back") was particularly high: 90% and 88.4% respectively (Table 2).

Back-PAQ Score

Mean initial Back-PAQ score for the overall sample was 28.3 (SD 6) (out of 50 points). For item 1 ("You can easily hurt your back") and item 2 ("You could hurt your back if you are not careful") a scores of 4 or 5 (suggesting misbeliefs) were frequent for item 1 (54.4%) and for item 2 (76.5%) on the pretest. This proportion increased further after viewing the video to 70.5% for item 1 and 85.2% for item 2 (Table 3). Mean Back-PAQ score after viewing the video (30.0, SD 6.75) increased significantly in the whole

sample (mean change: 1.74, SD 4.16; $p < 0.001$; Cohen d: 0.42). Analysis of the changes revealed that the score increased by ≥ 6.8 points (MDC) for 152 participants (11.4%). The mixed model used to compare change between the 4 subgroups revealed a significant group effect (higher initial total Back-PAQ score in the group with chronic pain than the other 3 subgroups) and a significant time effect characterized by an increase in the Back-PAQ score after viewing the video, with no group * time interaction effect (Table 4).

Intention to change behaviour post viewing

In response to the question "After watching this video, are you going to change how you perform your daily activities and will you pay more attention to protecting your back?", 55% (735/1338) of participants indicated that they would change their behavior, 23% (309/1338) were undecided and 22% (294/1338) stated they would not change.

Table 2 Ratings of agreement with the 7 main messages from the video clip (expressed as percentage of participants) (n=1338)

	Strongly agree (%)	Agree (%)	Unsure (%)	Disagree (%)	Strongly disagree (%)
Message 1	31.1	41	13.2	9.1	5.5
Message 2	35.7	31.9	12.9	12.6	6.8
Message 3	37.4	33.9	11.3	11.8	5.6
Message 4	26.2	27.4	20.7	19.4	6.4
Message 5	60.8	29.1	4.3	3.5	2.2
Message 6	46.8	38.2	7	5.2	2.9
Message 7	50	38.4	5.7	4.0	1.9

Message 1: When you get out of bed in the morning, try to keep your spine as straight as possible to avoid injuring your back.
Message 2: Avoid twisting/rotating your back to avoid injuring your back (e.g., when turning to pick up something behind you).
Message 3: Avoid bending forward without support to avoid injuring your back.
Message 4: When doing a daily task that requires bending over (e.g., brushing your teeth), always use your hand to support yourself to avoid hurting your back.
Message 5: When picking up an object from the ground, squat down instead of bending forward to avoid injuring your back.
Message 6: Avoid sitting in a slumped position and keep your back straight to avoid injuring your back.
Message 7: Avoid wearing a backpack with only one shoulder strap to avoid injuring your back

Discussion

The results of this study showed that viewing a video clip containing negative messages about LBP increased the extent of LBP-related misbeliefs immediately after viewing the video in a 20-50 age group. More than half of the participants stated that they would change their behavior to protect their backs after the viewing. Whether participants had current LBP or not, and whether they had (sub)acute or chronic LBP did not affect the magnitude of change in the Back-PAQ score post viewing.

The extent of LBP-related misbeliefs in this sample of participants from the French-speaking population of Europe was high, as shown by the mean initial total Back-PAQ score (29/50). These findings are consistent with those of previous studies in general populations [13, 14, 15, 16, 17, 18]. The high prevalence of misbeliefs was further confirmed by the relatively high degree of agreement of the participants with the messages conveyed in the video.

Despite the high initial score, the Back-PAQ score increased significantly after viewing, suggesting that the video reinforced and amplified participants' LBP-related misbeliefs. This increase was greater than the minimal detectable change (MDC) [30] for 11.4% of participants. Moreover, 55% of participants stated that they would consider changing how they performed their daily activities and would take more care to protect their backs after watching the video. It is particularly important to note that the largest changes occurred in those who had the fewest negative beliefs prior to viewing, highlighting the strong negative effect of the video on health-related beliefs in a 20-50 age group; the relatively high educational status of our sample does not seem to have protected them from these beliefs changes. These results have important implications for public health since mediatisation of health information can impact a large number of individuals [32].

Changes in beliefs following viewing were particularly marked for the first 4 items of the Back-PAQ, which are specific to beliefs about back fragility/protection. The initial scores for these items were frequently very high, reflecting the strong presence of negative beliefs in the general population, as found in previous studies [14, 17, 18]. Furthermore, these items were also the most negatively influenced by the video.

Comparison of the subgroups with (sub)acute or chronic pain, or a history of LBP revealed stronger misbeliefs in those with chronic pain, as has been found in previous studies [15, 17, 18, 33]. However, it was interesting that the magnitude of change in beliefs post viewing did not differ between the subgroups. A ceiling effect may have affected the results for the subgroup with chronic pain since mean initial Back-PAQ scores were higher in that group. Considering the high prevalence of misbeliefs in patients with chronic LBP, healthcare professionals should consider these patients as a specific subgroup for rehabilitation, with a clear need of educational approaches [34].

The harmfulness of everyday actions (getting out of bed, sitting or picking something up without keeping the back straight, rotating the trunk or bending forward) on the back was emphasised in the video clip. Yet, this information is contrary to guidelines [29, 35] which recommend that health professionals should avoid using certain words such as 'worn out', 'injury', 'weak', 'avoid leaning forward' because they might reinforce patients' unhelpful behaviours and resultant disability [10, 25, 36, 37]. The messages provided in the clip also contrast with recent studies [38, 39] and laboratory studies that showed that lifting a load in lumbar flexion with the knees straight does not increase stress on the lumbar segments [40, 41]. Furthermore, people with LBP usually overprotect their back: they perform functional activities with less movement of the back than asymptomatic individuals [42, 43]. This protective behavior is associated with negative beliefs [44]. Manual handling programs that teach individuals with LBP to limit lumbar movement when carrying loads do not reduce pain or functional disability [45].

Unfortunately, it is not uncommon for the media to convey information that is not aligned with scientific knowledge [8, 32]. Although improving beliefs is now considered a priority for the treatment of LBP [4, 10], the results of the present study confirm that the media can convey inappropriate messages that induce or reinforce negative beliefs within a sample of 1338 adults, and that this might lead individuals to adopt inappropriate behaviors.

Limitations

This study was original and evaluated beliefs regarding LBP in a large sample using a validated questionnaire. However, it has some limitations. Although we used varied methods of recruitment, selection bias may be present considering some exclusion criteria (e.g. lack of internet connection). The fact that these participants with LBP were younger than in other studies [2] and that this cohort had a relatively low mean age suggest an over-representation of a subgroup of age. This selection bias might have influenced the magnitude of our result. Indeed, the selected TV program may have been designed to target a subgroup of the population and different generations might be affected differently by messages conveyed in the media as their trust in media content may differ. Inclusion of a control group who did not view the video might have strengthened our

Table 3 Proportion of respondents who attributed each rating for the items of the Back-PAQ pre and post viewing (n=1338)

	Pre-viewing					Post-viewing					
	Score 1 (%)	Score 2 (%)	Score 3 (%)	Score 4 (%)	Score 5 (%)	Score 1 (%)	Score 2 (%)	Score 3 (%)	Score 4 (%)	Score 5 (%)	p-value
Item 1	14.5	12.6	18.4	25.6	28.8	10.4	9.9	9.3	27.3	43.2	< 0.001
Item 2	7.0	7.0	9.5	30.2	46.3	4.6	5.3	4.9	30.6	54.6	< 0.001
Item 3	45.5	20.6	18.8	11.4	3.8	26.1	22.9	20.4	21.0	9.6	< 0.001
Item 4	15.9	15.2	29.1	32.1	7.5	13.3	15.1	22.3	36.0	13.3	< 0.001
Item 5	46.1	22.6	14.9	11.6	4.7	45.8	19.7	18.5	10.6	5.4	0.14
Item 6*	47.3	31.1	13.2	5.7	2.8	45.4	30.6	14.1	5.8	4.2	0.004
Item 7*	10.0	27.3	24	13.6	25.1	9.6	25	25.6	15.7	24.1	0.28
Item 8*	10.4	26.9	28.8	12.0	22.0	8.8	26.1	27.7	14.4	22.9	0.002
Item 9	30.4	18.3	17.9	24.8	8.5	23.3	21.8	19.5	26.5	8.8	< 0.001
Item 10	20.3	16.9	17.8	32.5	12.6	20.3	18.8	19.2	28.8	12.9	0.09

Score 1 = false, score 2 = possibly false, score 3 = unsure, score 4 = possibly true, score 5 = true (scoring is reversed for items with *)

Table 4 Back-PAQ scores (means, SDs) with results of the mixed model (main effects for group, time, and group × time interaction).

	Asymptomatic – no history of LBP	**Asymptomatic – with history of LBP**	**(Sub)acute LBP**	**Chronic LBP**	**Main effect Time**	**Main effect Group**	**Group x Time Interaction**		
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	p-value	p-value	p-value	F	p-value
Pre viewing Back-PAQ score	27.5 (6.0)	27.7 (6.2)	27.9 (6.0)	29.8 (6.2)	(5.6)			10.11	<0.001
Post viewing Back-PAQ score	29.1 (6.8)	29.7 (7.0)	29.3 (7.1)	31.4 (6.0)	<0.001	<0.001 7	0.8	0.10	<0.001

conclusions, however we believe that it is unlikely that Back-PAQ score would have changed when completed twice with an interval of only 5 minutes (the duration of the video). The negative influence of the video may have been underestimated due to a ceiling effect related to the high prevalence of initial negative beliefs. It would also have been relevant to investigate a possible misbeliefs consolidation effect induced by the video clip by conducting a follow-up of the participants to determine if the changes in beliefs persisted or whether they actually changed their behavior after viewing the video clip. However, we did not perform such a follow-up since we included a closing statement in the questionnaire that was in line with current recommendations considering that it would have been unethical for participants to conclude the study after potentially reinforcing their negative beliefs. If such a follow-up is conducted in a further study, health status measurements should also be included to enable to the evaluation of possible nocebo effects [46, 47] of such kind of messages inducing negative beliefs conveyed in the media. Finally, our study did not investigate neither participants' perception to know if they perceived the popular French doctor as a healthcare provider or a journalist nor the specific influence of the selected media (a French one) which might have been different between the participants from France and those from other countries.

Conclusion

In conclusion, the results of this study demonstrate that a video clip shown on social media that conveyed negative messages about LBP reinforced LBP-related misbeliefs and may promote maladaptive behavior in a significant number of individuals. It is therefore essential for health professionals mastering the best practices in terms of LBP management to collaborate with the media providing health information to develop and share tools (such as video clips) providing evidence-based information. This study also confirms the high prevalence of LBP-related misbeliefs in the general population and thereby, the necessity for clinicians to explore patients' misbeliefs and their origin and to take them into consideration.

Conflict of interest

ML and JCB are employees of "AGIR à dom.", a non-profit home care provider. JCB has received grants, personal fees, and non-financial support from Philips healthcare, RESMED outside the context of the submitted work. JCB has also a patent with NOMICS SA. ML has received grants, personal fees, and non-financial support from Air Liquide Healthcare and SEFAM outside the context of the submitted work. JLP is supported by a research grant from the French National Research Agency (ANR-12-TECS-0010) in the framework of the "Investissements d'avenir" program (ANR-15-IDEX-02) and the "e-health and integrated care" Chair of excellence of the University Grenoble Alpes Foundation. JCB and JLP are co-inventors of a patent N°WO2016041025A1. The others authors (DN, CS, MCR, JPM, LL, EML, NM) have no conflicts to disclose linked to this work.

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EUROPEAN REHABILITATION JOURNAL | ORIGINAL

Feasibility of prescribed exercise programs in the rehabilitation of patients with cardiac amyloidosis

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ABSTRACT

Objective: We aimed to determine if prescribed exercise programs in rehabilitation of patients with cardiac amyloidosis was feasible and beneficial. **Methods**: This prospective monocentric pilot study was proposed to all adult patients, diagnosed with cardiac amyloidosis, and referred to the cardiac rehabilitation centre at the Henri Mondor University hospital (Créteil, France) between 2011 to 2015. All patients had clinical evaluations, laboratory tests, and echocardiographic examinations upon recruitment to the study. The cardiac exercise rehabilitation programme, in this study, comprised a baseline incremental system-limited exercise test followed by 20 endurance training sessions at a constant workload intensity. Cardiac exercise rehabilitation was deemed feasible if the patient completed the baseline test and $\geq$ 10 sessions without an adverse event. Patients with a relative increase of $\geq$ 16% in VO_{2max} and/or maximal workload were considered to have benefited from cardiac exercise rehabilitation. **Results:** Overall, 27 cardiac amyloidosis patients were recruited. Cardiac exercise rehabilitation was feasible in 19 (70%) and not feasible in 8 (30%). Of the 19 patients whom cardiac exercise rehabilitation was feasible, cardiac exercise rehabilitation benefited 9 (47%). This benefit was significantly associated with lower N-type pro-brain natriuretic peptide levels, lower creatinineamia, and higher left ventricular ejection fraction at baseline. **Conclusion:** Cardiac exercise rehabilitation is feasible and beneficial in selected patients with cardiac amyloidosis.

KEYWORDS: AL amyloidosis, amyloidosis, ATTRv amyloidosis, ATTRwt amyloidosis, cardiac exercise rehabilitation.

Introduction

There is evidence that cardiac exercise rehabilitation (CER) is safe and provides clinical benefits in patients with hypertrophic cardiomyopathy (HCM) [1, 2]. Recent diagnostic advances have allowed physicians to distinguish HCM from cardiac amyloidosis (CA) induced cardiomyopathy [3, 4, 5, 6, 7, 8, 9, 10]. Indeed, these cardiomyopathies share many signs and symptoms. However, despite the substantial therapeutic advances made for treating CA, the prognosis of CA patients is worse than that of HCM patients [11, 12]. In CA, data are required to demonstrate the benefit of CER and to identify patients most likely to benefit from CER. CA is a chronic disease characterized by the deposits of amyloid fibrils within the myocardium [13]. Besides amyloid fibril deposits in the heart, fibrils may also accumulate in other tissues and organs, including the kidneys, liver, soft tissues, and in peripheral motor and sensory nerves [14]. Amyloid infiltration of nerves leads to various disorders, including lumbar canal stenosis and sensory-motor neuropathies, that impair quality of life and exercise capacity. Patients with amyloidosis are classified according to the misfolded protein that forms the amyloid fibrils. The two most prominent types of systemic amyloidosis are light chain (AL) and transthyretin related (ATTR) amyloidosis. ATTR amyloidosis is further divided into hereditary ATTR (ATTRv) and wild-type ATTR (ATTRwt). The Secondary Prevention and Rehabilitation Section of European Association of Preventive Cardi-

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ology recently stated that cardiac rehabilitation, as secondary prevention, was the most cost-effective intervention in various cardiovascular disorders [15]. Cardiac rehabilitation did not only reduce cardiovascular mortality and morbidity but also increased patient quality of life. Cardiac rehabilitation comprises various interventions, including but not limited to dietary, psychosocial, and exercise interventions. Studies have shown that HCM patients benefits from CER [1, 2]. Wasserstrum et al. reported that exercise of moderate intensity was safe and was beneficial for most HCM patients [1]. Klempfer et al. reported that a supervised exercise program was safe and significantly improved symptoms, functional class (New York Heart Association classification), and functional capacity of HCM patients that remained symptomatic despite therapy [2]. To our knowledge, no study has yet assessed the benefits of CER in patients with CA. This paucity of data may partially be due to the poor prognosis of these patients. Exercise in CA patients may be hampered by neurological and renal symptoms, and by fatigue, known side effects of chemotherapy used to treat AL amyloidosis patients. A recent study showed the prognostic value of cardiopulmonary exercise testing, particularly VO2 max, combined with NT-proBNP levels in CA patients [16]. Exercise testing was also useful for assessing functional capacity, as well as circulatory and chronotropic responses in CA patients. We report the results of a pilot study examining the feasibility of CER in CA patients. The study aimed to assess the benefit derived from CER in CA patients.

Figures and Tables

Method

Study design

This study was designed as a prospective monocentric pilot study. All consecutive patients diagnosed with cardiac amyloidosis between 2011 and 2015 and referred to the cardiac rehabilitation centre at the Henri Mondor University Hospital in Créteil, France, were requested to participate in the study. The study was conducted according to the declaration of Helsinki and French law. The study was approved by the French ethics committee, 'Comité de Protection des Personnes', at the Henri Mondor University Hospital.

Study participants

Patients aged 18 years and older, with a confirmed diagnosed of cardiac amyloidosis according to current guidelines were eligible. Patients with light chain (AL) amyloidosis were diagnosed by a histological analysis of tissue biopsies with amyloid deposits stained for antibodies for kappa or lambda free immunoglobin light chains (FLC). While patients with ATTR were diagnosed with myocardial fixation on bisphosphonate scintigraphy, with or without a positive staining of biopsies using Congo Red and TTR antibodies. TTR genotyping was performed to distinguish between ATTRwt and ATTRv. All patients provided written consent prior to study participation.

Data collected at baseline

Patients with suspected amyloidosis underwent a comprehensive clinical evaluation, as well as laboratory tests and echocardiographic examinations. The data concerning demographics (age and sex), clinical data (weight and height), amyloidosis (type of amyloidosis), medical history (presence or not of a pacemaker, atrial fibrillation, and/or ventricular arrythmia), and laboratory tests (haemoglobin, N-terminal pro-brain natriuretic peptide [NT-proBNP], and creatinine blood levels) were collected. Moreover, the data from the echocardiographic examination (left ventricular ejection fraction [LVEF], left ventricular hypertrophy [LVH], ratio of early transmitral blood-flow velocity over tissue Doppler early diastolic mitral-annulus velocity [E/e], and systolic pulmonary arterial pressure [PAP]) were collected.

Cardiac exercise rehabilitation programme

The CER was supervised by a multidisciplinary team that included cardiologists, cardiovascular nurse specialists, physiotherapists, and exercise physiologists. The CER programme comprised a baseline incremental symptom-limited exercise test followed by 20 endurance training sessions at constant workload. A subgroup of patients performed cardiopulmonary exercise tests (CPET) before and after the training programme. When CPET was unavailable or not tolerated, conventional bicycle ergometers with simultaneous electrocardiographic recording were used. For the incremental exercise tests, the initial workload was 20 W, with an increase of 20 W every 2 minutes. For CPET, the increase was continuous (watt by watt), and for the conventional exercise test without CPET, the increase was stepwise. The training programme was group-based with a minimum of 3 sessions per week for outpatients and 5 sessions per week for inpatients. Each endurance training session consisted of 30 minutes of stationary cycling at a heart rate (HR) corresponding to the ventilatory threshold (VT) obtained during the baseline exercise test, according to standard cardiac rehabilitation recommendations [17]. When oxygen consumption was not measured, training HR was set at 60% 70% of the individual's HR reserve (maximal HR on incremental exercise test minus resting HR) [17]. In addition to the endurance training, all patients were systematically proposed supervised and guided resistance training 2-3 times per week. In patients with CPET, ventilation (VE), oxygen consumption (VCO_2) and carbon dioxide output (VO_2) were measured on a breath-by-breath basis via a computerised system (Medisoft, Belgium). In addition, maximal oxygen uptake (mL/kg/min), the first ventilatory threshold and ventilatory efficiency (VCO_2) were determined. Maximal oxygen uptake (VO_{2max}) was defined as the highest consecutive 30-second averaged value obtained during exercise test [18]. The first ventilatory threshold (measured by the Wasserman method) was defined as the point where ventilatory equivalent ratio for oxygen (VE/VO_2) starts to increase without concomitant increase in the ventilatory equivalent ratio for carbon dioxide (VE/VCO_2) [19]. During the programme, in all patients, intensity levels of exercise were systematically re-evaluated using the rating of perceived exertion (RPE) and were increased when RPE was <12 and decreased when RPE was >14 on the Borg's scale [20].

Data collected during cardiac exercise rehabilitation

During CER, maximal and resting HR, and maximum workload observed were collected for all patients. Also, the chronotropic reserve was measured during the incremental exercise tests, but not during the exercise sessions at constant workload intensity. The chronotropic reserve is the capacity of the heart to increase its rate during exercise or other metabolic demands. In addition, in patients who underwent cardiopulmonary exercise testing, the VO_{2max} and VE/VCO_2 ratio were collected. From the data, the percentage gain in maximal workload was calculated.

Study objectives and outcomes

Our main objective was to assess the feasibility of CER in patients with CA. The programme was considered feasible if patients performed a valid baseline exercise test and completed ≥ 10 of the scheduled training sessions without onset of an adverse event which limit the CER. Furthermore, we wanted to assess the functional benefit of CER in patients. A patient was considered to have benefited or responded to CER if there was a relative increase in VO2 max and/or maximal workload after CER of $\geq$ 16%. For patients, whose oxygen consumptions were not measured, a benefit or response was defined as an increase of $\geq 15\%$ in peak workload after CER.

Statistical analysis

Categorical data are reported as numbers with percentages and compared using Chi2 tests. While continuous data are expressed as means with standard deviations and compared using two-tailed Student's t-tests. A

p-value < 0.05 was considered statistically significant. Logistic regression was used to identify variables independently associated with the benefit from CER. Variables found to be significantly different ($p \leq 0.10$) in patients that benefited from CER compared to those without benefit. The following variables were included in the model: age, sex, and baseline levels of LVEF, serum creatinine, and log (NT-proBNP). Systolic pulmonary arterial pressure (PAP) was not included in the model since it was not measured in all patients. The cut-off limit for NT-proBNP was assessed using the Youden index [21, 22]. Statistical calculations were performed using the SPSS software package (SPSS Inc., Chicago IL, USA).

Results

Population characteristics

Between 2011 and 2015, 27 patients were prospectively recruited at Henri Mondor University Hospital in Créteil, France. Among the 27 patients with cardiac amyloidosis (CA) enrolled, 22 were male and the median age was 68 years, see Table 1. Sixteen (59%) had AL, 6 (22%) had ATTRv, and 5 (19%) had ATTRwt amyloidosis. Two-thirds of patients (18/27) had a cardiac pacemaker implanted. Median LVEF was 52% (IQR: 40-60), median LVH was 17 mm (IQR: 15-19), and the median ratio of early transmitral blood-flow velocity over tissue Doppler early diastolic mitral-annulus velocity (E/e) was 15 (IQR: 13-20). Concerning the baseline exercise capacities of the 27 patients: the median duration of the exercise test was 312 s (IQR: 165-474), the median resting HR was 80 bpm (IQR: 67-90), and the median maximum workload was 49 W (IQR: 30-78).

Cardiac rehabilitation

CER proved to be feasible in 19 patients (70%, Table 1). In contrast, 8 patients (30%) were not able to perform at least half of the 20 scheduled training session - the CER failure cohort. Three patients, all with AL amyloidosis, could not perform the baseline incremental exercise testing: 1 patient due to pericardial effusion and 2 patients due to severe fatigue. The remaining 5 patients completed baseline CER assessments but failed to complete at least 10 training sessions, a patient with each of the following conditions: hip pain (coxalgia), knee pain (gonalgia), dysautonomia, neuropathic pain, and refractory asthenia. Overall, the demographic and baseline characteristics in the CER feasible and CER failure cohorts were similar. However, in the CER feasible cohort more patients had pacemakers, 16/19 (84%) versus 2/8 (25%), p = 0.0061, and baseline NT-proBNP levels were lower, 2239 ng/L (IQR: 860-9460) versus 8600 ng/L (IQR: 4749-18358), p = 0.043. In the CER feasible cohort, compared to the CER failure cohort the exercise test duration was significantly longer, 360 s (IQR: 245-508) versus 134 s (IQR: 110-252); p = 0.015, and the chronotropic reserve was significantly higher, 53% (IQR: 15%-72%) versus 7% (IQR: 5%-26%), p = 0.036. It is noteworthy that age and type of amyloidosis were not significantly associated with CER feasibility.

Functional benefit

Of the 19 patients for whom CER was feasible, 9 patients (47%) had a functional benefit (Table 2). In these patients there were significant gains in maximal workload 34.7% (IQR: 19.6%-39.7%; p = 0.002). CPET were performed by 13 patients at baseline and by 15 patients at the end of CER. The presence or absence of meaningful functional benefit of CER was significantly associated with lower baseline NT-proBNP levels (872 ng/L [IQR: 493-1665] versus 7006 ng/L [IQR: 2600-18469]), lower serum creatinine (80.0 µmol/L [IQR: 73.5-123.5] versus 115.5 µmol/L [IQR: 97.3-263.3]), and higher LVEF (60% [IQR: 48%-62%] versus 39% [IQR: 32%-54%]), but not with the type of amyloidosis nor with LVH, see Table 2. It is noteworthy that none of the parameters measured during exercise, including VO2 max and chronotropic reserve, were significantly associated with the benefit of CER.

Identifying variables associated with a benefit from cardiac exercise rehabilitation Logistical regression, using age, sex, and baseline levels of LVEF, serum creatinine, and log (NT-proBNP), was used to identify variables independently associated with the functional benefit of CER. Of these variables, only log (NT-proBNP) was found to be associated with a benefit of CER: hazard ratio of 4.53; 214.2 (95% CI: 1.53-29993); p = 0.033. The Youden index identified a NT-proBNP level of <2700 ng/L as being associated with benefit from CER. The area under the curve (AUC) of the receiver operating characteristic (ROC) curve was 0.93 (95% CI: 0.82-1.00), p < 0.001. Moreover, sensitivity was 89% and specificity was 80%: with a positive predictive value (PPV) of 80% and a negative predictive response (NPV) of 89%.

Discussion

In our study, the first to our knowledge assessing CER feasibility in CA, CER proved to be feasible in 70% of the patients addressed to the cardiac rehabilitation centre. Compared to patients that could not complete the baseline assessment and at least half of the planned exercise sessions, significantly more patients for whom CER was feasible had pacemakers (84%) and baseline levels of NT-proBNP were significantly lower. Furthermore, the mean duration of the baseline exercise test was longer and the chronotropic reserve higher. Moreover, about half of them had a clinically meaningful functional benefit, with increased endurance and maximal workloads, when they completed the CER programme. In patients that benefited from CER, baseline levels of NT-proBNP and creatinineamia were lower, while LVEFs were significantly higher. In our analysis, a NT-proBNP cut-off of < 2700 ng/L proved useful to identify CA patients expected to benefit from CER. Our results reveal that patient selection is critical, both for CER feasibility and to identify patients most likely to benefit from CER.

Interestingly, our analysis did not identify the type of amyloidosis as significantly associated with CER feasibility. Of the 16 AL amyloidosis patients, CER was not feasible in 5 patients (31%): 3 failed to complete the baseline exercise test and 2 did not complete half of the scheduled exercise sessions. Among the 3 that failed to perform the baseline exercise test, 2 died within one month of enrolment. AL amyloidosis patients are often fragile with multiple organs infiltrated, about 80% of them have cardiac involvement, the severity of which determines survival [14, 23]. In AL patients with cardiac involvement, chemotherapy aims to rapidly eliminate amyloid precursors and to reduce amyloid deposits, thus improving cardiac function [14, 24]. However, chemotherapy with the associated side effects is difficult in these frail patients. The relative timing of CER with respect to chemotherapy needs to be evaluated for each AL patient, since performing CER while undergoing chemotherapy may be challenging. However, even though challenging, CER was feasible in 11 of the 16 AL patients. In AL patients where CER was feasible, cardiac involvement seems to be less severe as suggested by a significantly lower baseline mean NT-proBNP level in the CER feasible cohort, 2239 ng/L, compared to 8600 ng/L in the CER failure cohort. Our results suggest that CER is feasible in all types of CA, including selected AL amyloidosis patients with less severe cardiac involvement.

NT-proBNP may help select CA patients for whom CER is feasible and beneficial. In CA patients, NT-proBNP levels are often elevated due to hemodynamic burden [8]. NT-proBNP levels continue to increase with CA evolution and severity. Nicol et al. reported that NT-proBNP levels, and VO_{2max}, could predict death or heart failure-related hospitalisations in CA patients [16].

In addition to NT-proBNP levels, other selection criteria need to be assessed. The 6-minute walk test (6MWT) is clinically useful to assess cardiovascular fitness and could help select patients for CER [25]. Also, systematic screening for severe orthostatic disorders could identify patients with exercise intolerance and for whom CER will probably not be

Table 1 Baseline patient characteristics according to feasibility of cardiac exercise rehabilitation.

Variables	All	CER feasible cohort	CER failure cohort	p-value*
	n = 27	n = 19	n = 8	
Clinical characteristics:				
Age, years	68 (61-78)	66 (61-79)	72 (58-78)	0.94
Male sex	22 (81)	15 (79)	7 (88)	1.00
Body Mass Index, kg/m2	24.5 (21.8-27.6)	24.5 (21.4-27.5)	24.4 (22.1-29.5)	0.89
Type of amyloidosis				0.098
AL	16 (59)	11 (58)	5 (63)	
ATTRwt	5 (19)	2 (11)	3 (38)	
ATTRv	6 (22)	6 (32)	0 (0)	
Pacemaker	18 (67)	16 (84)	2 (25)	**0.0061**
Atrial fibrillation	12 (44)	10 (53)	2 (25)	0.24
Ventricular arrhythmia**	10 (37)	6 (32)	4 (50)	0.41
Laboratory:				
Haemoglobin, g/dL	12.6 (11.2-13.6)	12.2 (9.9-13.5)	13.1 (11.8-14.3)	0.243054
2239	8600	**0.043**		
NT-proBNP, ng/L	3054	2239	8600	**0.043**
	(1012-10794)	(860-9460)	(4749-18358)	
Serum creatinine, µmol/L	113 (84-162)	104 (80-141)	147 (104-214)	0.22
Echocardiography:				
LVEF, %	52 (40-60)	52 (38-60)	53 (43-59)	0.82
LVH, mm	17 (15-19)	16 (14-20)	18 (16-19)	0.52
E/e	15 (13-20)	16 (13-21)	13 (9-20)	0.52
Systolic PAP, mmHg	40 (30-44)	39 (31-44)	40 (24-43)	0.41
Baseline exercise test:				
Duration, s	312 (165-474)	360 (245-508)	134 (110-252)	**0.015**
Resting HR, bpm	80 (67-90)	79 (66-96)	84 (71-89)	0.89
Maximum workload, W	49 (30-78)	60 (40-82)	30 (25-45)	0.063
Chronotropic reserve, %	29 (7.8-51)	53 (15-72)	7 (5-26)	**0.036**

Continuous variables are expressed as median (IQR) and discrete variables as number (%). AL amyloidosis: light-chain amyloidosis; ATTRv amyloidosis: hereditary transthyretin related amyloidosis; ATTRwt amyloidosis: wild-type transthyretin related amyloidosis; bpm: beats per minute; CER: cardiac exercise rehabilitation; E/e: ratio of early transmitral blood-flow velocity over tissue Doppler early diastolic mitral-annulus velocity; HR: heart rate; IQR: interquartile range; LVEF: left ventricular ejection fraction; LVH: left ventricular hypertrophy; NT-proBNP: N-type pro-brain natriuretic peptide; PAP: pulmonary arterial pressure; W: watt. *p-values <0.05 are in bold. **Ventricular arrythmia is defined as having ≥ 3 consecutive beats at a rate >100 beats per min.

Table 2 Patient characteristics according to functional benefit from cardiac exercise rehabilitation.

Variables	Benefit	No benefit	p-value*
	n = 9	n = 10	
Clinical characteristics:			
Age, years	64 (56-73)	74 (65-85)	0.95
Male sex	6 (67)	9 (90)	**0.0001**
Body Mass Index, kg/m2	24.5 (20.6-28.1)	25.2 (23.6-27.6)	0.72
Type of amyloidosis, AL vs ATTR	5 (55.6)	6 (60.0)	0.61
With pacemaker	8 (88.9)	8 (80.0)	0.54
With atrial fibrillation	6 (66.7)	4 (40.0)	0.24
Biology characteristics			
Haemoglobin, g/dL	12.9 (9.4-13.6)	12.0 (11.4-13.4)	0.80
NT-proBNP, ng/L	872 (493-1665)	7006 (2600-18469)	**0.001**
Serum creatinine, µmol/L	80.0 (73.5-123.5)	115.5 (97.3-263.3)	**0.035**
Echocardiography-characteristics:			
LVEF, %	60 (48-62)	39 (32-54)	**0.004**
LVH, mm	15.0 (14.0-18.3)	16.5 (15.0-19.0)	0.84
E/e	13.5 (11.5-25.0)	17.0 (14.0-20.5)	0.32
Systolic PAP, mmHg	31.5 (29.3-36.8)	43.5 (40.3-45.5)	0.010
Baseline exercise test:			
Duration, s	360 (218-513)	358 (224-511)	0.99
Resting HR, bpm	81 (72-93)	76 (63-97)	0.60
Maximal HR, bpm	49 114 (97-146)	113 (84-143)	0.72
% of maximal theoretical HR	76 (65-87)	81 (58-94)	0.84
Maximum workload, W	70.0 (37.5-86.0)	46.5 (37.5-76.3)	0.40
VO_{2max}, mL/kg/min	11.7 (9.6-13.7)	8.6 (6.6-16.7)	0.37
VE/VCO_2	40.0 (35.0-43.5)	41.0 (36.0-75.0)	0.53
Chronotropic reserve, %	46.7 (28.6-63.0)	24.5 (8.1-70.0)	0.40
Exercise training			
Number of training sessions	20.0 (18.5-39.5)	18.0 (13.25-26.0)	0.45
Gain in maximal workload, %	34.7 (19.6-39.7)	0 (-8.9 to 12.0)	0.002
Final exercise test			
Duration, s	496 (422-617)	334(290-656)	0.41
Resting HR, bpm	72 (64-81)	77 (76-93)	0.19
Maximal HR, bpm	117 (94-152)	118 (104-131)	0.96
% of maximal theoretical HR	69.5(64.3-98.5)	83.0 (73.0-95.0) 0.61	
VO_{2max}, mL/kg/min	13.0 (11.7-15.7)	7.9 (6.0-20.9)	0.66
VE/VCO_2	36.5 (32.8-42.0)	39.0 (34.5-57.0)	0.33
Chronotropic reserve, %	55.8 (45.2-83.9)	53.3 (11.8-72.4) 0.54	

Continuous variables are expressed as median (IQR) and discrete variables as number (%). AL amyloidosis: light-chain amyloidosis; ATTR amyloidosis: transthyretin related amyloidosis; bpm: beats per minute; E/e: ratio of early transmitral blood-flow velocity over tissue Doppler early diastolic mitral-annulus velocity; HR: heart rate; IQR: interquartile range; LVEF: left ventricular ejection fraction; LVH: left ventricular hypertrophy; NT-proBNP: N-type pro-brain natriuretic peptide; PAP: pulmonary arterial pressure; VO2 max: maximal volume of oxygen uptake; VCO2 max: maximum volume of carbon dioxide exhaled; VE: ventilation; VE/VCO2: ventilatory equivalent ratio for carbon dioxide; W: watt. *p-values <0.05 are in bold.

feasible [26].

In systemic amyloidosis, cardiac involvement depends on the subtype [27]. As mentioned above, about 80% of AL patients have cardiac involvement [14, 23]. In ATTRwt amyloidosis, the heart is almost always affected and about two-thirds have heart failure at diagnosis. In contrast, ATTRv amyloidosis patients have various phenotypes depending on the TTR mutation, with cardiac involvement in about 40% of the patients.

When amyloid fibrils infiltrate the heart, patients develop heart failure leading to reduced exercise capacity [16]. Nichol et al. observed that, VO_{2max}, circulatory power (VO_{2max} multiplied by peak systolic blood pressure), and oxygen pulse (VO_2 divided by HR) were diminished in CA patients during exercise, due to low exercise inotropic reserve and restrictive heart filling patterns. It should be noted that he VO_{2max} during exercise reflects not only the capacity of muscles to metabolise oxygen but also the subject's cardiac, vascular, and pulmonary capacities.

Furthermore, Nichols et al. observed that the VE/VCO_2 slope was increased in CA patients, reflecting the reduced cardiac output reserve during incremental exercise. This is possibly due to restrictive haemodynamics in CA patients with increased pressure in the left ventricle and in the pulmonary circulation during exercise. Haemodynamics of CA patients, at rest, using right heart catheterization have been assessed. Indeed, Russo et al. reported that haemodynamic profiles were similar in AL and ATTR patients: high resting right and left ventricular filling pressures with low cardiac outputs [28]. Clemmensen et al. reported that during exercise CA patients had severely reduced inotropic myocardial reserve and increased right and left ventricular filling pressures, measured by right heart catheterization [29]. Interestingly in CA patients, VO_{2max} during incremental exercise was strongly related to the peak cardiac index (cardiac output indexed to body surface area). Overall, CA patients during exercise have a diminished cardiac output, with lower VO_{2max}, increased VE/VCO_2 slope, and a lower exercise capacity

Chronotropic incompetence (CI), the inability of the heart to respond to exercise, often occurs in patients with cardiovascular diseases. Chronotropic incompetence results in impaired exercise tolerance, reduced peak exercise capacity, diminished quality of life, and predicts all-cause mortality. Consequently, chronotropic incompetence in CA patients impacts clinical management, including the feasibility of CER. Indeed, a study assessed chronotropic incompetence during exercise in 40 HF patients equipped with wearable Holter-accelerometers, 50% of patients were chronotropic incompetent [30]. In chronotropic incompetent patients the 6MWT distance was significantly shorter and physical activity intensity, measured by the age-predicted maximal heart rate value, was significantly reduced. Similarly, Nicol et al. reported that 51% of CA patients assessed by CPET were chronotropic incompetent and that HR response during exercise correlated with VO_{2max}.

Interestingly, in our study a large proportion of CA patients for whom CER was feasible had rate responsive pacemakers, suggesting that modern pacemakers facilitate CER in CA patients. The significantly higher chronotropic reserve in patient that performed CER is probably at least partly due to the rate adaptive pacing of the pacemaker and not to the physiological HR response to exercise.

Amyloidosis is a complex disorder with various cardiac and extracardiac manifestations that makes healthcare management challenging. Despite the substantial therapeutic advances made in recent years, prognosis for amyloidosis and particularly CA patients remains poor. However, the improved diagnosis and treatment of chronotropic incompetence, conduction disorders, and arrhythmias has increased the feasibility of CER in CA patients. Moreover, in our study extracardiac amyloid involvement did not appear to limit CER. There is evidence that CER benefits patients with HCM, thus we can expect that CER will benefit selected CA patients: increasing quality of life and possibly survival.

CA patients undergoing CER can expect to increase their VO_{2max} with possible survival benefits. Indeed, CA patients with lower VO_{2max} ($\leq$13 mL/kg/min) had a significantly increased risk of heart failure hospitalizations and death [16].

Limitations

Our study was designed as a pilot study to provide exploratory results assessing the feasibility and benefit of CER in CA patients and thus has several limitations. Our sample size was small and our results exploratory. Furthermore, we only examined the functional benefits after a 20-sessions training period. The long-term benefits of CER, including functional benefits, and the impact on quality of life, morbidity, and mortality beyond the CER programme will need to be assessed. Cardiopulmonary exercise testing was not available for all patients, thus limiting the statistical power of the results based on gas exchange measurements. Finally, the patients included in this study were on average younger than CA patients referred to our centre, therefore there is a potential selection bias.

Conclusion

CER is feasible and beneficial in selected patients with CA. Further studies are required to assess the benefit, in terms of quality of life and other outcome, of CER in CA.

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Data availability statement

The data that support the findings of this study are available from the corresponding author, TD, upon reasonable request.

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French translation and validation of the Jefferson Scale of Empathy - Health Professions Student version

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ABSTRACT

Background: Background: Jefferson Scale of Empathy is one of the most widely used tools worldwide to assess empathy. The extended version for Health Professions Students (JSE HPS) has not yet been translated into French. **Objective:** The aim of our study was to translate the JSE HPS into French and assess the psychometric properties of this new version (JSE HPS Fr). **Methods:** The JSE HPS was translated according to international recommendations. The main psychometric qualities (test-retest reliability, internal consistency, floor and ceiling effects and construct validity) were studied in a sample of physiotherapy students. Participants provided general information (age, gender, year of study) and completed the JSE HPS Fr and the Questionnaire of Cognitive and Affective Empathy (QCAE). Participants were also asked to complete the JSE-HPS-Fr again one week later to assess its test-retest reliability. **Results:** 408 students (161 males and 247 females; mean age: 21.3 years) participated. The JSE HPS Fr demonstrated good test-retest reliability for the total score (ICC=0.81) and good internal consistency (α Cronbach: 0.79). The JSE HPS also showed good convergent validity with the QCAE questionnaire (r=0.41, p<0.05). No floor or ceiling effects were observed. **Conclusions:** The results indicate that the JSE HPS Fr is a valid and reliable tool to assess the level of empathy of French-speaking physiotherapy students.

KEYWORDS: empathy, validity, surveys and questionnaires, physiotherapy, students

Introduction

Empathy is a commonly used term, but the concept is also often misunderstood concept. It is commonly defined as the ability to "put yourself into someone else's shoes", but it is much more complex than simply matching the emotions of others with your own. Decety et al.[1] defines empathy as the ability to feel an appropriate emotion in response to that expressed by another, while clearly distinguishing between self and other (i.e. being aware of the source of the emotion and being able to decode the emotion of the other) and being able to regulate one's own emotional responses. Empathy is therefore about trying to understand a person's feelings and demonstrating that understanding through appropriate verbal and non-verbal responses.

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In an article about the effects of empathy, Lecomte describes in 2010 [2] several benefits when a health care practionner (HCP) listens to a patient in an empathetic way: patients' satisfaction, improvement of physical health, psychological well-being, compliance with prescriptions, and a decrease in legal proceedings in case of medical errors. According to Howick el al.[3], empathy could even have similar effects to pharmacological treatments by decreasing pain by 1-2 points on a visual analogue scale. Empathy is therefore an essential dimension at the heart of the interaction between HCPs (doctors, physiotherapists, nurses, psychologists, etc.) and patients.

Numerousquestionnaires have been developed to assess empathy in the general population, as well as in specific populations (such as adolescents or health professionals)[4]. Among these, the Jefferson Scale is one of the most widely used tools, worldwide. Developed by Hojat et al.[5], the original Jefferson Scale of Empathy (JSE) measures empathy in physicians, and all other health professionals involved in patient care in a clinical setting (JSE HP-version [6]). A student version was later

developed to evaluate empathy in medical students (JSE S-version [7]) and another one for health professions students (JSE HPS-version [8]). The JSE has been translated into 59 languages/dialects and has been used worldwide (in at least 85 countries) https://www.jefferson.edu/academics/colleges-schools-institutes/skmc/research/research-medical-education/jefferson-scale-of-empathy.html. Conversely, the extended versions of this questionnaire have been less frequently translated.

As no French version of the JSE HPS is curently available, the aims of this study are to translate the Jefferson Scale of Empathy – Health Professions Student (JSE HPS) into French, and to validate this new version (JSE HPS Fr) in a population of physiotherapy students.

Method

The present study was carried out in two stages. The first one was the cross-cultural translation of the English JSE-HPS into a French version (JSE HPS Fr). The second stage was designed to examine the main psychometric properties of the JSE HPS Fr. The JSE was used in this study with permission from Thomas Jefferson University.

Cross-cultural translation

After contacting the Jefferson University to obtain the original scale (in English) and request their permission to translate it into French, the translation of the questionnaire followed several phases according to Beaton et al.[9]. The first step was to translate the scale from its original language (i.e. English) into the desired language (i.e. French). Two translators (bilingual, native French speakers, one being a physiotherapist and the other a psychologist), each provided a translation of the original version independently. The two translators then met to compare their translations and discuss the issues raised during the process. This stage led to a synthesis of the translations and to a first JSE HPS Fr version.

The next step consisted of a back-translation carried out independently, by two bilingual English-French speakers (one being a psychologist and the other a professor). who translated the first JSE HPS Fr version back into English, (blind condition, i.e. without having seen the original English version). Then, the two back-translations were compared to the original version during a meeting with the research team including all translators and an expert in the field (linguist). Differences in translation were discussed and, if there was any doubt about the meaning of the items, the authors of the original scale were contacted to ensure their correct understanding. A linguist checked the wording of the items and their conformity to French culture without sacrificing the key concepts. Finally, a pilot study was conducted with 22 Belgian healthcare university students to test the clarity and understanding of the items. If necessary, some changes were carriedout and the final version of the JSE HPS Fr was then created and submitted to Jefferson University for final approval.

Evaluation of the psychometric properties of the JSE HPS Fr

Following the principles of the Consensus-based Standards for the Selection of Health Status Measurement Instruments (COSMIN) recommendations [10], the following psychometric properties of the French version of the empathy scale (JSE HPS Fr) were examined: test-retest reliability, internal consistency, floor and ceiling effects and construct validity.

Participants All physiotherapy students enrolled during the year 2020-2021 at the University of Liège (n=914) were invited to participate in the study (from early bachelor to master). Participants who agreed to take part, signed a consent form before data collection. The study was granted ethics approval from the Ethical Committee of the University of Liège.

Experimental procedure Participants were recruited through email and social networks as the majority of the courses were online distance learning due to the Covid-19 pandemic. They were invited to complete a battery of questions via a secure platform. It included some demographic information (age, gender and year of study), the JSE HPS Fr and another empathy rating scale i.e., the Questionnaire of Cognitive and Affective Empathy (QCAE), to examine the JSE HPS Fr's construct validity. One week after, students who had completed the first form were invited to complete the JSE HPS Fr a second time to assess its test-retest reliability. Participants were given a unique number to identify them in the test-retest situation.

Questionnaires The JSE HPS Fr is composed of 20 questions: ten on perspective, eight on compassion and two on the therapist's ability to see things from the patient's point of view. Each question is rated on a 7-point Likert scale ranging from 1 ("Strongly Disagree") to 7 ("Strongly Agree"). The total score is obtained by adding up the score of each item. The higher the scorethe greater the empathy (score range: min=20 to max=140). For some questions (No. 1, 3, 6, 7, 8, 11, 12, 14, 18, and 19) the scores must be reversed to calculate the total score [5]. The QCAE, developed by Reniers et al.[11], consists of 31 items for which participants are asked to indicate their degree of agreement using a 4-point Likert scale ("Strongly agree", "Somewhat agree", "Strongly disagree" and "Strongly disagree"). The QCAE has five subscales (two for cognitive empathy and three for affective empathy). The total score ranges from 31 (reflecting low empathy) to 124 (reflecting high empathy). We used the French validated version of the QCAE [12].

Statistical analysis

All statistical analyses were carried out using the IBM SPSS Statistics 27.0.1.0 software. Normal distribution of quantitative variables was checked by using the Shapiro-Wilk test. Quantitative variables that were normally distributed were expressed as mean ± standard deviation (SD), and quantitative variables that were not normally distributed were expressed as median (and interquartile range, percentile 25-75). The results were considered statistically significant at the 5% critical level.

The floor and ceiling effects were analyzed by calculating the percentage frequency of the lowest or highest possible score achieved by respondents. Floor and ceiling effects of less than or equal to 15% were considered acceptable [13].

One-week test-retest reliability was assessed using the intraclass correlation coefficient (ICC, two-way mixed, absolute agreement) and the 95% confidence interval. Test–retest reliability improves as the ICC approaches 1, and an ICC of greater than 0.7 is indicative of an acceptable reliability [13]. The standard error of measurement (SEM, which provides a range around the observed value in which the theoretical true value can be found) and the minimal detectable change (MDC, which indicates the amount of change that needs to be measured to be sure that the change measured is real and not due to a potential measurement error) of the JSE HPS Fr were also calculated. The standard error of measurement was calculated by dividing the standard deviation of the difference between test and retest scores by the square root of 2 ($SDdiff/\sqrt{2}$). The smallest detectable change was calculated by multiplying $1.96 * SEM * \sqrt{2}$ [14]. The Limits of Agreement (LOA) were also determined according to the method of Bland and Altman, which makes it possible to evaluate a bias between the differences in means and to estimate an interval of agreement in which 95% of the differences between test and retest lie [15].

Cronbach's alpha coefficient was used to estimate the internal consistency. We also assessed the impact of deleting each item on the internal consistency. Cronbach's alpha coefficient varies between 0 and 1 and allows us to appreciate the degree to which the items of a questionnaire measure the same attributes or dimensions. The more the items are related to each other, the higher the alpha coefficient. A Cronbach's alpha between 0.70

Table 1 Characteristics of the population and responses to questionnaires (n=408)

	Mean ± SD	n, %
Age (year)	21.3 ± 2.51	
Gender		
Women		247 (60.5)
Men		161 (39.5)
Year of study		
1^{st} year of bachelor		91 (22.3)
2^{nd} year of bachelor		130 (31.9)
3^{rd} year of bachelor		85 (20.8)
1^{st} year of master		102 (25.0)
JSE HPS Fr questionnaire		
Total score	107 ± 12.4	
Perspective domain	53.5 ± 7.42	
Compassion domain	45.5 ± 6.15	
Putting Yourself in the patient's shoes	9.0 ± 2.48	
QCAE questionnaire		
Total score	89.3 ± 8.3	
Cognitive empathy		
Perspective taking	29.7 ± 4.39	
Online simulation	27.1 ± 3.15	
Affective empathy		
Emotional contagion	11.4 ± 2.37	
Proximal responsivity	12.1 ± 2.13	
Perpheral responsivity	9.08 ± 1.32	

and 0.95 reflects good internal consistency [13]. Correlation coefficients were also calculated to measure the correlation between the total score of the questionnaire and scores of individual domains. Spearman or Pearson correlations coefficients were used depending on the distribution of the variables (normal or not). Correlation coefficients less than 0.3 were considered as weak correlations; between 0.3 and 0.6 as moderate correlations and higher than 0.6 as strong correlations [16].
Finaly, construct validity was also assessed by the Spearman or Pearson correlations according to the distribution of variables. Three hypotheses were developed to test correlations between the JSE and the QCAE questionnaires. Significant and positive correlations were therefore expected between: 1) the total scores of both questionnaires; 2) the compassion domain of the JSE and the affective empathy domain of the QCAE, and 3) the perspective domain of the JSE and the perspective domain of the QCAE. Construct validity was considered as good if at least 75% of the hypotheses were confirmed.

Sample size

A sample size power calculation was possible for reliability analysis since this is one of the most frequently used measurement properties. Considering an alpha error of 0.01, a statistical power of 0.9, and an expected ICC of 0.85, a total of 100 participants was required [17]. This sample size is in line with COSMIN recommendations [10].

Results

Translation

The translation of the JSE HPS into French generally went well but some issues were encountered. Firstly, initially, the translators hesitated between "professionnels de la santé", "soignants" and "prestataires de soins de santé" to translate "health care providers". In order to remain faithful to the original version, they opted for "prestataires de soins de santé". However, after back-translation, they decided to replace this term with "professionnels de la santé" to keep the idea of "health care" and to avoid including mutual insurance companies or similar organisations in the notion of providers. Secondly, in the translation, the terms "attention" and "attentiveness" were both translated as "attention". After back-translation, the expression "The fact of being attentive to" was used for "attentiveness" to mark the difference, however subtle, with "attention". The latter refering more to an action, whereas "attentiveness" is more a quality of the person. Third, for the translation of "cured" in item 11, three proposals were put forward: "soignées", "guéries" and "traitées" and the first one was adopted. During back-translation, this term was translated as "cured" and "treated". The translators finally chose "cured" in order to keep the idea of complete healing found in the verb "cure" as opposed to "treat" which refers to an improvement of the condition, without curing. Finally, for question 18 we decided to contact Jefferson University for further clarification about the meaning. Translation was therefore finalised according to their advice. After providing a first translated version, the French linguist made some suggestions and remarks to achieve a first final version of the JSE HPS Fr. This version was further pre-tested on 22 students. Only slight additional changes were necessary to obtain the final version of the French translation. The Jefferson University approved the final version.

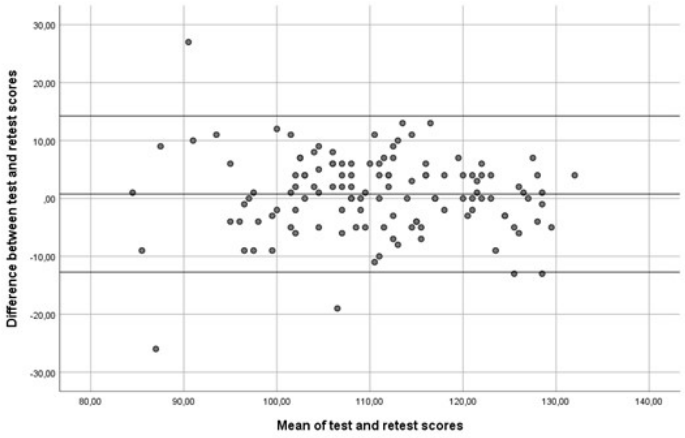

Figure 1 Figure 1: Bland and Altman plot for test-retest reliability

Characteristics of the population

Four hundred and eight physiotherapy students (45% of the approached sample) of the University of Liège (ULiège) participated in the study (161 males and 247 females) with a mean age of 21.3 ± 2.51 years (min 18 - max 34) **Table1**.

Psychometric properties

Floor and ceiling effects None of the respondents obtained the minimum score of 20 or the maximum score of 140 on the questionnaire, indicating the absence of floor and ceiling effects.

Table 2 Internal consistency and test-retest reliability

	Internal consistency (n=408)			Test-retest reliability (n=124)
	Cronbach's alpha	Cronbach's alpha for total scale if domain removed	correlation with total score	ICC (95% CI)
Total score	0.79			0.81 (0.74 - 0.86)
Perspective	0.69	0.69	0.82, p<0.001	0.78 (0.70 - 0.84)
Compassion	0.72	0.66	0.84, p<0.001	0.71 (0.61 - 0.78)
Putting yourself in the patient's shoes	0.64	0.80	0.31, p<0.001	0.62 (0.50 - 0.72)

Internal consistency Cronbach's alpha was 0.79 for the entire questionnaire, indicating good internal consistency (**Table 2**). Lower Cronbach alphas were found for individual domains; 0.69 for the "Perspective" domain, 0.72 for the "Compassion" domain and 0.64 for the "Putting yourself in the patient's shoes" domain. However, positive and significant correlations were found between individual domains and total score; r=0.82 between total score and "Perspective" domain, r=0.84 between total score and "Compassion" domain and r=0.31 between total score and "Putting yourself in the patient's shoes" domain (all p-values <0.01).

Construct validity Significant and positive correlations were found between the total score of the JSE HPS Fr and the total score of the QCAE (Spearman r=0.41, p<0.001, i.e. moderate correlation); between the Compassion domain of the JSE HPS Fr and the Affective empathy scale of the QCAE (Spearman r=0.16, p=0.001, i.e. weak correlation); and between the Perspective domain of the JSE HPS Fr and the Perspective Taking domain of the QCAE (Spearman r=0.31, p<0.001, i.e. moderate correlation).

Test-retest reliability 124 students completed the JSE HPS Fr again one week later and were included in the test-retest analyses. The ICC indicated good reliability for the total score (ICC 0.81, 95%CI 0.74-0.86). A low test-retest reliability was found for the "Putting yourself in the patient's shoes domain" (ICC 0.62, 95% CI 0.50-0.72) (**Table 2**). Regarding the total score, a SEM of 4.87 points and an MCD of 13.5 points were measured. The mean difference between test and retest was of 0.758 (LOA inf -12.7, LOA sup 14.2) (**Figure 1**).

Discussion

The scientific literature on healthcare often addresses the concept of empathy. However, this topic is still insufficiently explored, especially in physiotherapy [18]. Yet, empathy is considered essential to create a positive relationship between therapist and patient, allowing in particular to improve the patient's experience and adherence to treatment [19]. Raising awareness of the importance of empathy among (future) health professionals is therefore necessary from the beginning of their studies. Although questionnaires examining the level of empathy already exist in French, the translation of the JSE-HPS [8, 20] was relevant given its specific adaptation to allow the assessment of medical and paramedical students.

The translation process followed the methodology recommended by Beaton et al. [9]. No major difficulties were encountered during this process. Furthermore, 408 students participated in the validation study. Results revealed an acceptable construct validity, estimated by comparing the JSE-HPS to the QCAE questionnaire. Despite being significant, correlations were weak to moderate. This could be explained by the difference in the population targeted by the two tools. The QCAE was indeed designed to assess cognitive and affective empathy in the general population [11] whereas the JSE-HPS is used to assess the level of empathy in students in the health fields [6]. Internal consistency (assessed using the Cronbach's alpha coefficient) was good for the total score. Internal consistency of individual domains was over 0.7 for the "Compassion" domain but lower than 0.7 for both other domains. Our results highlighted a lower internal consistency compared to that reported for the English version (0.89)[6]. The test-retest reliability of the JSE-HPS Fr was studied on 124 students who completed the Jefferson scale a second time one week later. The sample size used is larger than that generally recommended for testing the reproducibility of a questionnaire. The one-week delay between the test and the retest is commonly used for questionnaires validation [13]. The reliability of the total score, assessed by means of the ICC, showed good test-retest reliability of the scale. Our results confirm those of Hojat et al. who reported ICCs around 0.70-0.80 in almost all studies conducted in the USA and abroad with the JSE [6]. The ICC for the 'Perspective' and 'Compassion' scores (0.78 and 0.71 respectively) indicates moderate reliability, while the ICC for the 'Putting yourself in the patient's shoes' score suggests lower reliability (0.59). A SEM of 4.87 points and a MDC of 13.5 points were measured. The minimal detectable change means that the total score of the scale would have to change by at 13.5 points before we can be sure that this score improved/deteriorated. To our knowledge, this is the first time that the SEM and the MDC values were provided for the JSE-HPS version of the questionnaire.

Few studies have examined the level of empathy in physiotherapy students [21, 22, 23] and, to our knowledge, this is the first study in French-speaking Belgium. The total empathy score reached 107.8 ± 12.4 points. In most studies using the JSE, the mean scores of the different versions of the scale are around 112[6], which suggests that the score in our study is slightly lower than the average. One hypothesis for this is that our study was performed during the Covid-19 pandemic. It is therefore possible that the empathy score was lower due to stress and lower quality of life during this period but also because teaching was mainly conducted remotely, as those factors have been shown to influence empathy levels [24, 25].

An American study showed that physiotherapy students had a slightly but significantly higher empathy score on the JSE-HPS than other health disciplines [26]. This difference in scores could be explained by the fact that physiotherapy students are in contact with patients from mid-way through the bachelor's degree. On the contrary, another study [27] highlighted lower scores for physiotherapists compared to HCP in other disciplines such as psychology, psychiatry or paediatrics, which could be explained by the fact that physiotherapists do not focus on the concept of empathy as much as psychologists, psychiatrists and paediatricians during their training.

Reassuringly, the vast majority of our 408 respondents (96.49%) seem to have a biopsychosocial (and not purely biomechanical) approach by agreeing with the idea that attention to patients' emotions during the interview with the patient is important. On the other hand, it appears surprising that a large proportion of them seem to find it difficult to put themselves in the patient's shoes, as suggested by the poor scores on items three and six of the "Putting oneself in the patient's shoes" subscale.

Some studies have shown that empathy is not a stable personality trait and can be improved by educational interventions [28, 29, 30]. Training to maintain and improve empathy in physiotherapy students at the University of Liege could be relevant.

Strengths and limitations of the study

Despite its originality and the size of the sample used, our study has certain limitations. A selection bias cannot be excluded given the health context. The students could not be met directly and were invited to fill in an online form. Thus, only students interested in empathy could have responded to our survey. Although it was explained that there were no right or wrong answers to the scale used, a desirability bias cannot be ruled out either.
Also, sensitivity to change was not measured because of the cross-sectional design of this study. Further studies should be conducted to examine the sensitivity to change of the scale and to investigate the level of empathy with students from other health care fields.

Conclusion

Our study allowed us to develop a French version of the Jefferson Scale of Empathy - Health Professions Students (JSE-HPS) with moderate convergent validity, good test-retest reliability, moderate internal consistency, and no floor or ceiling effects.

Statement and declaration

Authors' contribution

The authors confirm contribution to the paper as follows: Study conception and design: CM, PEN, FS and CD. Translation: CM, CD, PEN and FS. Back translation: FJG, JF, CM, CD, PEN and FS. Data collection: PEN and FS. Analysis and interpretation of results: CM, PEN, FS, CD, CB, FJG and JF. Draft manuscript preparation: CM and CB. All authors reviewed the results and approved the final version of the manuscript.

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Disclosure statement

Authors declare that they have no conflict of interest with regard to the content of this manuscript.

Ethics

The study was approved by the Ethical Committee of the University of Liège.

Consent to participate

Informed consent was obtained from all individual participants included in the study

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Data availability statement

The french version of the questionnaire is available by the Thomas Jefferson University.

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EUROPEAN REHABILITATION JOURNAL | ORIGINAL

The construct validity of the Ricci-Gagnon questionnaire to assess physical activity level: a prospective study

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ABSTRACT

Background: The physical activity level of individuals has gained interest in the medical field in the last decades. It can be assessed using validated questionnaires. The Ricci-Gagnon questionnaire has been designed for this purpose but has never been validated. The aim of this study was to verify the construct validity of the Ricci-Gagnon questionnaire to assess physical activity level. **Method**: Healthy participants completed the Ricci-Gagnon questionnaire and the International Physical Activity Questionnaire (IPAQ) short form reflecting the physical activity level as the evaluated construct. The questionnaires were scored as recommended. **Results**: Results were analysed for 93 participants. Age was inversely correlated to the Ricci-Gagnon (rho = -0.223, p = 0.033) and IPAQ scores (rho = -0.206, p = 0.049). Only the score for vigorous intensity activities in the IPAQ was inversely correlated with age (rho = -0.412, p < 0.001). Logarithmic regression showed that the Ricci-Gagnon questionnaire predicted the physical activity level determined by the IPAQ short-form whatever the age-group. However, the coefficient of determination indicated that the variability in the dependent variable was explained by the logarithmic relationship with the independent variable, mainly for the 20-39 age-group (F=40.378, R^2=0.582, p<0.001). This relationship was poorly explained for the 40-59 years (F=4.209, R^2=0.123; p=0.049) and the 60-80 years age-groups (F=11.567, R^2=0.300, p=0.002). Agreement between the 2 questionnaires for physical activity level was poor (K = 0.203, 95%CI: 0.050 to 0.356, p=0.001) and age-group influenced the agreement.**Conclusion**: The Ricci-Gagnon questionnaire has construct validity for the assessment of physical activity level in people under 40 years old.

KEYWORDS: physical activity, assessment, Ricci-Gagnon questionnaire, international physical activity questionnaire short-form, construct validity

Introduction

Physical activity is defined by the World Health Organization (WHO) as "any bodily movement produced by skeletal muscles, that requires energy expenditure" [1]. It includes leisure time, transport, and work. Physical activity level is related to the health-related quality of life of adults [2, 3]. As such, the World Health Organisation has defined a minimal recommended daily physical activity level. Regular physical activity prevents and reduces the risk of various medical conditions affecting quality of life and mortality, such as hypertension, coronary heart disease, stroke, diabetes, breast and colon cancer, and depression [4, 5, 6, 7]. The benefits of physical activity are non-linearly related to the level of physical activity [8]. This means that the reduction in the relative risk of mortality continues to increase with higher volumes of physical activity. All these elements justify the need for tools to assess physical activity level.

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Physical activity level can be assessed using objective or subjective

Table 1 Participant characteristics and test scores

	Total (n=93)	20-39 years (n=31)	40-59 years (n=32)	60-80 years (n=30)	comparison by age-group (p-value)
Characteristic					
Age (years)	56.1 (23.3-87.4)	25.3 (23.3-40.2)	56.3 (44.8-60.2)	73.7 (63.2-87.4)	0.001[a,b,c]
Sex ratio (M/F)	40/50	18/13	8/24	14/16	0.025
30s STST (repetitions)	16.5 (8-30)	21 (9-28)	17.5 (11-30)	12 (8-30)	0.001[b,c]
Ricci-Gagnon Questionnaire					
Total score (points)	25 (11-36)	29 (13-36)	24 (12-35)	23 (11-35)	0.070
Inactive/Active/Very active (n)	18/70/5	3/25/3	8/23/1	7/22/1	0.430
IPAQ Short-Form					
Total score (MET-min/week)	1958 (258-9546)	2265 (370-9546)	2189 (258-7662)	1386 (330-6396)	0.129
Low/Moderate/High level (n)	9/54/30	2/18/11	4/18/10	3/18/9	0.911

[a]:20-40 years. vs 40-60 years ; [b]:40-60 years vs 60-80 years; [c]:20-40 years vs 60-80 years

measurements. Objective measurements quantify energy expenditure using physiological parameters (e.g., heart rate or oxygen consumption), or body movement (accelerometery or, multi-sensor measurements). Subjective measures include diaries and self- assessment questionnaires. As with all measurement tools, questionnaires require validation before use. Many questionnaires are available for use in children and adults [9]. Unfortunately, they are not all fully validated. The COnsensus-based Standards for the selection of health status Measurement Instruments (COSMIN) describes the whole process of validation [10], from linguistic validation to the verification of psychometric properties [11].
The International Physical Activity Questionnaires (IPAQ) that includes 4 different questionnaires is the reference questionnaire for physical activity assessment [12]. However, this questionnaire has several disadvantages: the need to rate the overall activity intensity, the difficulty for the individual to quantify the number of hours of physical activity and the complex scoring system [13]. The Ricci-Gagnon questionnaire has been developed in French and is frequently used in French speaking countries. Unfortunately, it has never been validated. Construct validity, which is the degree to which the scores of a questionnaire are consistent with hypotheses based on the assumption that the questionnaire validly measures the construct to be measured, should be evaluated for this questionnaire [11].

The aim of this study was to verify the construct validity of the Ricci-Gagnon questionnaire to assess physical activity level. We assumed that the IPAQ-short form measures physical activity (the evaluated construct).

Method

Subjects

This prospective observational study followed the Statement for STrengthening the Reporting of OBservational studies in Epidemiology (STROBE). Participants were prospectively recruited in the street in December 2019. The inclusion criteria were aged over 18 years, native French-speaking, literate, with no chronic disease and not taking any medication (based on self-declaration). The exclusion criteria were any physical incapacity or cognitive disorder. Three groups were constituted by age (20-39, 40-59, and < 60 years) to ensure a homogeneous age distribution in the total sample. All participants performed a 30s sit-to-stand test (STST). This test has been validated to quantify functional lower limb strength in people with COPD [14, 15]. The study was approved by the regional Ethics Committee from Cliniques universitaires Saint-Luc and Université Catholique de Louvain in Brussels (2018/04JUL/274) and followed the current guidelines for Clinical Good Practice. All participants provided written informed consent for participation.

Design

Participants completed the 2 self-report questionnaires assessing physical activity: the Ricci-Gagnon questionnaire as the evaluated questionnaire and the IPAQ-short form reflecting physical activity level as the evaluated construct.

Ricci-Gagnon questionnaire This questionnaire includes 9 questions assessing habits related to physical activities (Appendix 1). Sedentary behaviour (1 item), leisure activities (including sport) (4 items) and activities of daily life (4 items) are assessed. Scores for each question range from 1 to 5 points and the total score ranges from 9 to 45 points. The higher the total score, the greater the physical activity level. A total score > 18 points is considered as inactive, between 18 and 35 points as active and > 35 points as very active.

IPAQ short-form This questionnaire is valid and reliable in French [12]. It includes 4 sets of questions about the number of days and time spent performing moderate (4 MET) or vigorous intensity (8 MET) physical activity and walking (3.3 MET) for at least 10-min at a time during the last 7 days. The total score is expressed as MET-min per week. Three categories are defined:
- High level if vigorous-intensity activity on at least 3 days and accumulating at least 1500 MET-minutes/week, or 7 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 3000 MET-minutes/week.
- Moderate level if 3 or more days of vigorous activity of at least 20 minutes per day, 5 or more days of moderate-intensity activity or walking of at least 30 minutes per day, or 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min/week.
- Low level if none of the above categories. The IPAQ short-form was self-completed by all participants using the standardised instructions provided with the questionnaire.

Statistical analysis The sample size was calculated using a correlation coefficient of 0.30 (corresponding to the median value of all the coef-

ficients found in the different IPAQ short-form validation studies [9]), with a power of 80% and an alpha level of 0.05. A 10% missing data rate by group was used. The number of required participants was 33 per group. Data were analysed using SPSS 27.0 for Windows (IBM Software). A descriptive analysis was done for participant characteristics and the results of the 2 questionnaires. Results are described in tables using the median, minimum and maximum, and the 95% confidence interval. A ceiling or floor effect was respectively considered if more than 15% of participants achieved the highest or the lowest possible score [16]. Because of the distribution of the results for the 2 questionnaires, a logarithmic regression was used to verify the construct validity of the Ricci-Gagnon questionnaire to assess overall physical activity level. The coherence between the activity level categories was verified using Cohen's kappa coefficient (k). This was run to determine if there was an agreement between the physical activity levels measured by the 2 questionnaires. The level of agreement was determined according to the guidelines from Altman [17] as follows: 0-0.20 = poor; 0.21-0.40 = fair; 0.41-0.60 = moderate; 0.61-0.80 = substantial; 0.81 - 1.00 = almost perfect. The percentage of exact agreement was calculated and corresponded to the percentage of participants who were assigned the same physical activity level category by both questionnaires. Data by age-group were compared using an ANOVA or a Chi-squared test. A p-value < 0.05 was considered as statistically significant

Results

Ninety-nine participants were consecutively recruited. Six were subsequently excluded because of physical incapacity (n = 3) or incomplete questionnaires (n = 3). The characteristics of the sample and the results are shown in (**Table 1**). Functional lower limb strength was reduced in the 2 older age-groups. No ceiling or floor effect occurred. The total score obtained using the Ricci-Gagnon questionnaire decreased with increasing age-group although the total weekly physical activity level was not different. Age was inversely correlated with the Ricci-Gagnon (rho = -0.223, p = 0.033) and IPAQ short-form scores (rho = -0.206, p = 0.049). Only the score for vigorous intensity activities in the IPAQ short-form was inversely correlated with age group (rho = -0.412, p < 0.001).

The logarithmic regression showed that the Ricci-Gagnon questionnaire predicted the physical activity intensity determined by the IPAQ short-form whatever the age-group (**Figure 1**). However, the coefficient of determination indicated that the variability in the dependent variable was explained by the logarithmic relationship with the independent variable, mainly for the 20-39 age-group (F=40.378, R^2=0.582, p<0.001). This relationship was poorly explained for both the 40-59 years (F=4.209, R^2=0.123; p=0.049) and the 60-80 years age-groups (F=11.567, R^2=0.300, p=0.002).

Agreement between the 2 questionnaires regarding physical activity level was poor (K = 0.203 (95%CI: 0.050 to 0.356) (p=0.001)). The percentage of exact agreement was 58%. Disagreement was highest between the active and the high-level categories from the Ricci-Gagnon questionnaire and the IPAQ, respectively (23% disagreement). Age-group influenced agreement. Agreement between the 2 questionnaires for the physical activity level for the two younger age-groups was poor to fair (K = 0.278, 95%CI: -0.004 to 0.560, p=0.017) and K = 0.211 (95%CI: -0.020 to 0.442, p=0.046) for 20-39 and 40-59, respectively. There was no agreement for the older age-groups (K = 0.100, 95%CI: -0.169 to 0.369, p=0.382).

The 30s STST result was correlated with the total Ricci-Gagnon questionnaire score (rho=0.348, p=0.001), the total weekly physical activity intensity (rho=0.247, p=0.018), and total weekly physical activity with a high intensity (rho=0.435, p<0.001). It was not correlated with total weekly physical activity with low (rho=0.123) or moderate (rho=0.055) intensity.

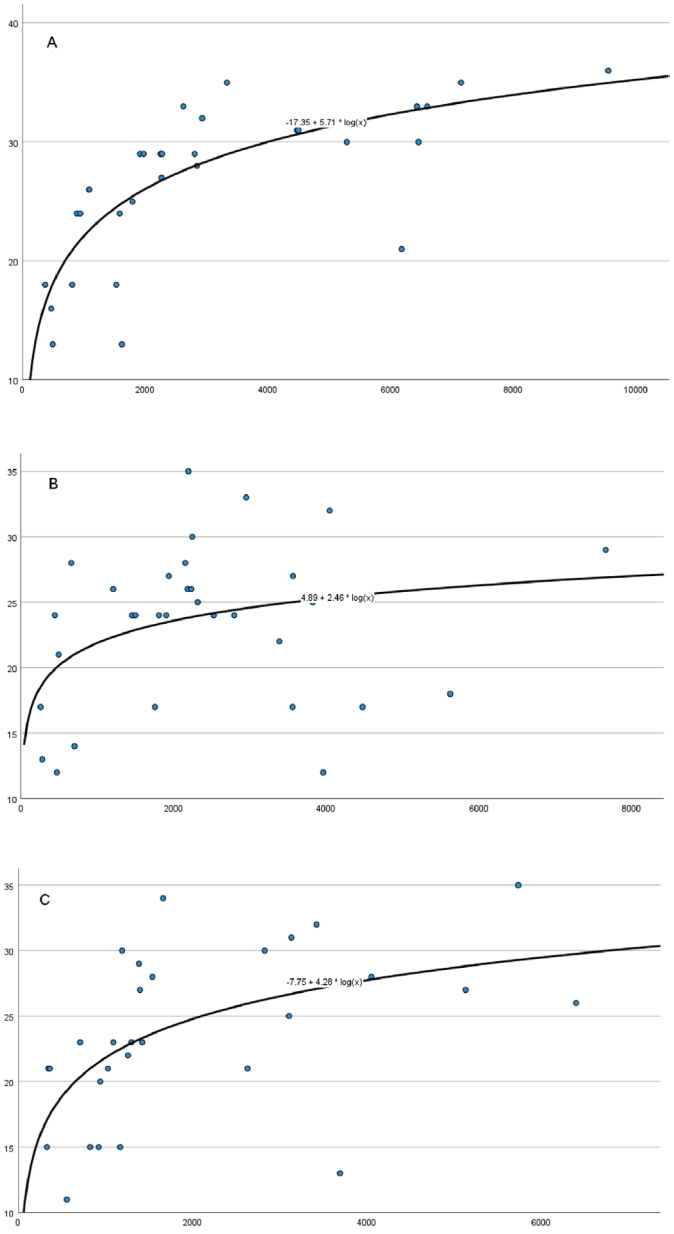

Figure 1 Figure 1:Relationship between the Ricci-Gagnon (X axis) and IPAQ (Y axis) scores for each age group: 20-40 years (n=31) (Panel A), 40-60 years (n=32) (Panel B), and 60-80 years (n=30) (Panel C)

Discussion

This study verified the construct validity of the Ricci-Gagnon questionnaire to assess physical activity level. We found that the questionnaire had construct validity for people under 40 years old.

The logarithmic regression was used to fit the relationship between the results of the 2 questionnaires because the curve for the total weekly physical activity intensity accelerated rapidly then slowed. The model fitted better in the 20-39 age-group, demonstrating the construct validity of the Ricci-Gagnon questionnaire to assess physical activity of different levels determined by the IPAQ short-form in this age-group. Indeed, the coefficient of determination of 0.58 indicated that 58% of the variability in the Ricci-Gagnon questionnaire results could be explained by the

logarithmic relationship with the different total weekly physical activity levels determined by the IPAQ short-form. However, the relationship was not satisfactory for the 2 other age-groups (lower coefficients of determination).
The agreement between the 2 questionnaires for the descriptive categories of physical activity level was poor, as illustrated by the Cohen's kappa value and by the same response category of physical activity level lower than 60%. Substantial disagreement was observed between the active and the high-level categories from the Ricci-Gagnon questionnaire and the IPAQ short-form, respectively. That means that the discriminant validity for physical activity level was low and that the Ricci-Gagnon questionnaire cannot be used as a surrogate for the IPAQ short-form to discriminate between physical activity levels. This is because the descriptions of the different categories by the 2 questionnaires are not substitutable due to differences in the scoring of the categories. The IPAQ short-form focuses more on the intensity of different types of physical activity in the scoring than the Ricci-Gagnon questionnaire. The Ricci-Gagnon questionnaire focuses more on global life activities by summing the different items of the questionnaire, including activities of daily life and physical leisure activities. Agreement between the questionnaires decreased with participant age. This can be explained by the fact older people have expectedly lower scores because older adults generally engage in less vigorous, shorter duration physical activity than younger adults as illustrated by the fact the only correlation between age and the IPAQ short-form score was for vigorous intensity activities. Less than one quarter of older adults engage in regular physical activity [18].

The lack of medical screening of participants could be considered as a limitation with regards to verification of the healthy status of those included. Recruitment was based on self-report. The number of movements performed during the 30s STST was in line with the normative values for older adults in Germany [19] and slightly higher than those for adults in Spain [20]. This indicates that the lower limb strength of the recruited subjects was within normal ranges. This test has been used to discriminate between sufficient and insufficient physical activity levels in adults [21]. Therefore, it was not surprising to find a correlation between the 30s STST, and the total scores obtained with both the Ricci-Gagnon questionnaire and the total weekly physical activity intensity determined by the IPAQ short-form. Indeed, muscle strength is associated with physical activity level [15]. Moreover, the correlation between the 30s STST and the time spent performing vigorous intensity physical activity but not moderate or low activity can be explained by the 30s STST power of discrimination between people with sufficient and insufficient physical activity levels [21] or those who exercise regularly and those who do not [15].

In conclusion, we found that the Ricci-Gagnon questionnaire only had construct validity for people under 40 years old. This easy and quick questionnaire can be used routinely to assess physical activity level in this group. However, the discriminant validity of the Ricci-Gagnon questionnaire was not confirmed for the different categories of physical activity level.

Statement and declaration

Authors' contribution

The authors confirm contribution to the paper as follows: Gregory Reychler: Conceptualization; Methodology, Formal analysis; Investigation; Writing - Original Draft; Supervision Anne-Sophie Petit: Methodology, Formal analysis; Writing - Review and Editing Frank Aboubakar: Methodology, Formal analysis; Writing - Review and Editing Giuseppe Liistro: Methodology, Formal analysis; Writing - Review and Editing Antoine Fremault: Methodology, Formal analysis; Writing - Review and Editing Gilles Caty: Methodology, Formal analysis; Writing - Review and Editing Marc Beaumont: Methodology; Writing - Review and Editing

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Disclosure statement

All authors declare they have neither financial nor non-financial interests.

Ethics

The study was approved by the regional Ethic Committee in Cliniques universitaires Saint-Luc and Université Catholique de Louvain in Brussels (2018/04JUL/274)

Consent to participate

Informed consent was obtained from all individual participants included in the study

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EUROPEAN REHABILITATION JOURNAL | PROTOCOL

Training older adults to inhibit the automatic attraction to sedentary stimuli: A cognitive-bias-modification protocol

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ABSTRACT

Background: Current interventions aimed at reducing physical inactivity mainly rely on reflective processes that focus on increasing conscious motivation. However, while these interventions are successful in increasing intentions to be active, their effect on actual behaviour is weak. Recent evidence, in line with the Theory of Effort Minimization in Physical Activity (TEMPA), suggests that this inability to translate intentions to be physically active into action may be explained by positive automatic reactions to stimuli associated with sedentary behaviour. These automatic reactions can be particularly strong in older adults, who are more likely to associate physical activity with fear, pain, or discomfort. **Objective**: The objective of this study is to test the effect of an intervention that trains older adults to inhibit their automatic attraction to sedentary stimuli in order to increase physical activity. **Methods**: Older adults will be enrolled in a placebo-controlled, double-blind study with 1, 3, 6, and 12-month follow-up. Participants will be randomised (1:1 ratio) to receive 12 sessions of cognitive bias modification training based on a go/no-go task in an experimental or control (placebo) condition. The primary outcome will be the number of steps per week. Secondary outcomes will include automatic approach-avoidance tendencies toward sedentary and physical activity stimuli, explicit affective attitudes toward physical activity, physical fitness, and quality of life. **Discussion**: The study is expected to inform public health policies and improve interventions aimed at increasing physical activity levels in older adults.

KEYWORDS: Attentional bias, ageing, exercise, health behaviour, sedentary behaviour

Background

Over the past two decades, society has encouraged people to be more physically active [1, 2, 3]. As a result, most people are now aware of the benefits of regular physical activity and have the intention to exercise [4]. However, this intention is not sufficient, as exercise plans are often not carried out [5, 6]. Despite the gradual increase in efforts to promote physical activity over the years, people are becoming less active. From 2010 to 2016, the number of inactive adults worldwide increased by 5%, and currently affects more than 1 in 4 adults (1.4 billion people) [7]. This gap between intention and action is a challenge that health professionals must address to counter the pandemic of physical inactivity [8, 9].

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Physical activity is one of the most important contributors to health, reducing rates of cardiovascular disease [10], cancer [11], hypertension [12], diabetes [13], obesity [14], and depression [15]. This wide spectrum of benefits is particularly important for older adults who often experience structural and functional decline in multiple physiological systems. Physical activity can reduce and delay the effects of this age-related health decline [16]. However, more than 60% of older adults in the Americas are physically inactive [17]. Current interventions designed to increase physical activity in older adults rely primarily on reflective processes by providing rational information about the health benefits of a physically active lifestyle [18]. From this perspective, changing conscious goals should lead to substantial change in behaviour [19]. However, meta-analyses indicate that these interventions are more effective at changing intentions than actual behaviour [6, 20]. Thus, new interventions targeting alternative processes (e.g., automatic processes) are needed.

The Theory of Effort Minimization in Physical Activity (TEMPA)

suggests that an automatic attraction to behaviours that minimize energetic cost could explain the inability to translate intentions to be physically active into actions [21, 22, 23]. The repeated failure to counteract this automatic attraction is thought to partly explain the pandemic of physical inactivity [24]. Consistent with TEMPA, experimental results suggest that avoiding sedentary stimuli requires more inhibitory control than avoiding physical activity stimuli [25]. In addition, other results suggest that avoiding sedentary stimuli requires more brain activity associated with inhibitory control than approaching sedentary stimuli [26]. These results have been supported by large-scale epidemiological studies [25, 27, 28] and are consistent with the notion that these sedentary stimuli are attractive and therefore difficult to avoid [29]. Therefore, as further epidemiological research suggests [30], cognitive resources may be required to avoid sedentary cues and increase the engagement in physical activity.

Engagement in physical activity is governed not only by reflective processes, but also by automatic affective reactions that operate outside of conscious awareness [31]. For example, in active individuals, stimuli associated with physical activity attract attention [32, 33], elicit positive affective reactions [34, 35], and activate approach tendencies [36]. These automatic affective reactions are thought to facilitate the translation of intention into action [37, 38]. From this perspective, physical inactivity is the result of an imbalance between strong negative affective automatic reactions to stimuli associated with physical activity, and a relatively weaker intention to be physically active. This imbalance between reflective and automatic processes can be particularly pronounced in older adults, who are more likely to experience an excessive fear of physical activity [39, 40]. Therefore, older adults may be particularly responsive to, and benefit most from, interventions that target automatic affective responses to physical activity and sedentary stimuli.

Interventions that target automatic reactions to health-related stimuli have been shown to be successful in changing behaviour [41, 42, 43, 44, 45, 46, 47]. For example, interventions have been used to retrain the automatic reaction to alcohol [42]. Using a joystick, patients were repeatedly asked to avoid alcohol-related images on a screen and to approach non-alcohol-related images. Results showed that adding a cognitive bias intervention to regular treatment reduced relapse rates by 9% to 13% one year after discharge [42, 43, 44]. Similar interventions have also been shown to be useful in influencing smoking [45], social anxiety [46], eating [47], and physical activity behaviour [48, 49]. Other types of interventions have been used to improve affective processes and promote physical activity [50, 51, 52]. These interventions have shown mixed results in increasing physical activity, with small effect sizes. However, none of these studies have targeted the processes that inhibit our tendency to minimize effort. The proposed study will fill this gap by testing the effect of a cognitive bias intervention based on a go/no-go task to strengthen the processes that counteract the automatic approach to effort minimization.

Objectives and Hypotheses

The primary objective of this study is to examine the effectiveness of an intervention aimed at training inhibition of automatic attraction to sedentary stimuli to increase usual levels of physical activity (i.e., number of steps per week) in older adults. The secondary objective is to test the effects of the intervention on reflective and automatic processes underlying physical activity behaviour, physical functioning, and quality of life. We hypothesise that, relative to participants in the comparison group, participants in the intervention group will have higher levels of physical activity (pre-intervention vs. 1-week post-intervention) (H1). Moreover, we hypothesize that, relative to participants in the comparison group, participants in the intervention group will decrease their automatic approach tendencies towards sedentary behaviours (H2a) and their automatic avoidance tendencies towards physical activity behaviours (H2b). Finally, we hypothesize that participants in the intervention group will improve their physical fitness (H3a) and quality of life (H3b), compared with participants in the comparison group.

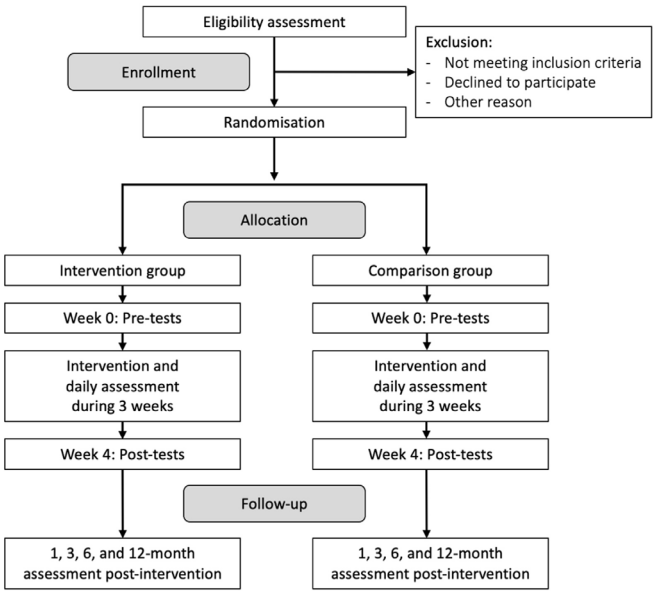

Figure 1 Study design

Methods

Study Design and Settings

Our study follows a placebo-controlled, double-blind design with a 12-month follow-up (**Figure 1**).

Participants

Adults aged 60 years and older will be included in the study [53].

Recruitment

Recruitment will be by emails to senior clubs and groups as well as posters at Non-Governmental Organizations (NGO) and Community centers in the area of Ottawa, Ontario, Canada. Interested participants will be asked to contact the principal investigator of the study. They will then be invited to attend a face-to-face meeting aimed at increasing their intention to be physically active based on the Ask-Assess-Advise approach [18] and to inform them about the study. Participants will receive a copy of the informed consent form prior to the first meeting to inform them about the study. Interested participants will be given the opportunity to ask any questions over the phone or at the meeting before written informed consent is obtained. Consent will only be obtained when the participant fully understands what the study entails and agrees to participate. If they decide to participate, they can withdraw from the research and/or refuse to answer any questions at any time without negative consequences. To assess a potential effect of sex, we will attempt to recruit a similar number of males and females. We will also explore the moderating effect of sex on the effect of the intervention.

Eligibility

To participate in this study, volunteers must be 60 years of age or older and able to understand instructions in English or French. The Mini-Mental State Examination (MMSE) [54] will be used to assess cognitive

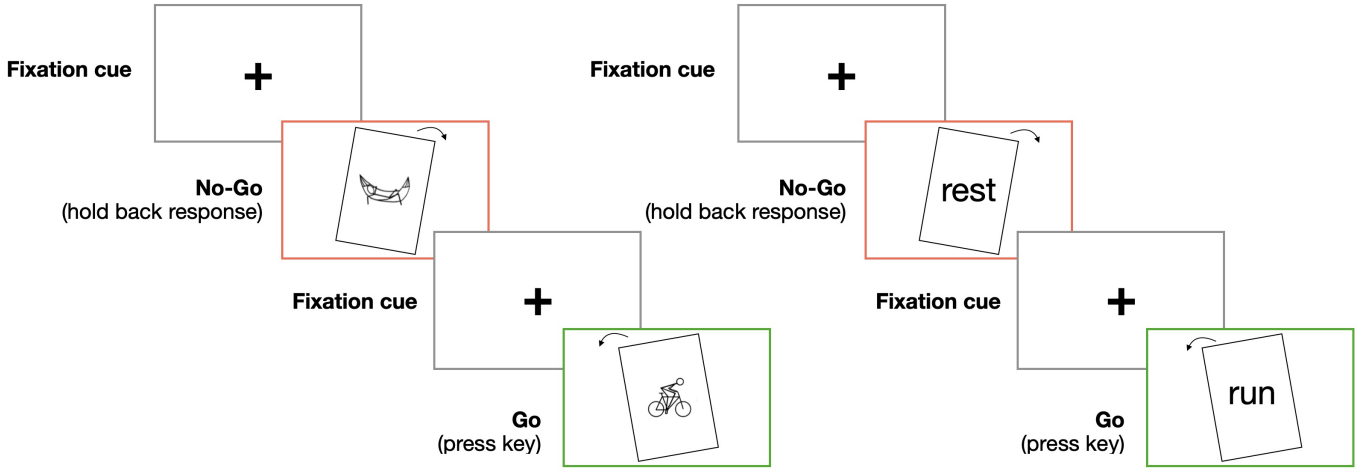

Figure 2 Go/No-go task based on images (left panel) and words (right panel)

function, as poor cognition may affect participants' ability to follow instructions [55, 56, 57]. Potential participants with an MMSE score below 24 will not be eligible for inclusion. Other exclusion criteria are diagnosis of psychiatric disorders or neurological pathologies (e.g. stroke, Parkinson's or Alzheimer's disease, dementia), inability to perform the training program or understand the protocol, motor deficit that requires external assistance to undergo physical activity, physical health status that contraindicates physical activity (e.g. severe cardiac or respiratory disease), and alcohol or drug dependency.

Sample Size Calculation

For power calculation, our intervention implements a between-subject design and random-effects statistical models (i.e., t-tests). The power calculation is based on the primary outcome (i.e., number of steps). Based on estimates of the effect size of interventions using the go/no-go task (g = .39) [47], a desired statistical power of 0.9, and an alpha of 0.05 [58], a sample size calculation in G*Power [59] indicated that a minimum of 140 participants per arm is needed. We expect a loss to follow-up of 10% to 20% at 1 week after the intervention, and a loss of 30 to 40% over 1 year. Thus, a minimum of 392 participants will be recruited.

Ethical Approval and Considerations

This research will be performed in accordance with the Declaration of Helsinki. The study was approved by the University of Ottawa (Canada) Research Ethics Boards (H-09-22-8453). Potential participants will be informed of study details, including procedures, risks and benefits, confidentiality, and the voluntary nature of participation, before signing the consent form. To follow good research practices [59] and to ensure that the research output is quickly and fully accessible to the scientific community and the public, the manuscript will be published as a preprint (e.g., MedRxiv, SportRxiv) and de-identified data, materials and scripts will be made public (e.g., Zenodo) and freely available in open repositories with a Digital Object Identifier (DOI) or another permanent identifier (e.g., Zenodo). Results will be published in scientific journals selected based on their contributions to good research practices [60] and be disseminated at international conferences.

Intervention

Cognitive-Bias Modification Task: The intervention is based on a go/no-go task in which older adults are instructed to quickly decide whether to respond to a stimulus [61]. The task has been adapted to train inhibitory processes that counteract the automatic attraction to sedentary stimuli and promote the automatic approach to stimuli related to physical activity. Specifically, a rectangle containing an image or a word is presented on a screen.

Intervention Group: In the intervention group, older adults are instructed to restrain their actions when the rectangle is tilted to the right and to respond by pressing a key on the keyboard when the rectangle is tilted to the left, irrespective of the content of the rectangle. The rationale for pressing a key on the keyboard solely in response to the direction of the tilt of the rectangle, as opposed to the content of the rectangle, is to ensure that the nature of the training is implicit. To train inhibitory processes that counteract the automatic attraction to sedentary behaviour, 90% of the right-tilted rectangles (counterbalanced across participants) will contain a picture or a word related to sedentary behaviour (**Figure 2**). To promote the automatic attraction to physical activity, 90% of the left-tilted rectangles will contain a picture or a word related to physical activity.

Comparison Group: In the comparison group, the instructions will be identical, but the percentage of physical activity and sedentary stimuli will be equal in each tilt condition (i.e., 50% sedentary stimuli and 50% physical activity stimuli in both right and left-tilted rectangles).

Experimental Protocol: After the face-to-face meeting, the older adults who agree to participate will receive a physical activity tracker (ActiGraph GT9X-BT) [62]. Participants will be trained on the go/no-go task for 3 weeks (4 sessions/week) (**Figure 3**). Each training session will consist of two blocks of 400 trials for a total of 30 min. To assess the effect of the intervention, primary and secondary outcomes will be collected the week before the first session, the week after the last session of the intervention, and 1, 3, 6, and 12 months post-intervention. At each assessment session, secondary outcomes will be assessed in a randomised order across participants.

Allocation and Blinding

Research assistants and participants will be blinded to group allocation. At the end of the trial, the success of the participant blinding will be assessed by asking the participants to guess which group they were in, including a percentage of certainty. The success of research assistants' blinding will be assessed by asking each research assistant if they were able to identify the group (control vs. intervention) when collecting data. Randomisation will be based on computer-generated permuted blocks. To ensure that the research team is blinded to the randomisation, an

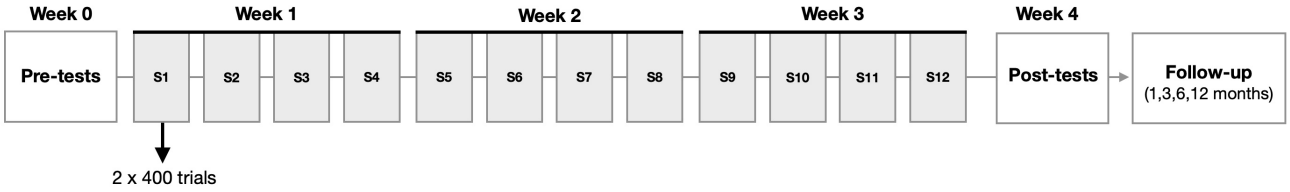

Figure 3 Protocol timeline

independent staff member will perform the randomisation. The participant's identification number will be used to determine the order of randomisation. Participants will be randomised in a 1:1 ratio between the intervention and comparison group. No unblinding is planned during the trial, as we do not see any reasons that would require either the participants or the researchers to know which group the participants were assigned to. However, if requested by the participants, unblinding will be allowed at the end of the trial.

Outcomes

Primary Outcome

The project focuses on device-based measures of physical activity because self-reported measures can be influenced by memory and social desirability [63, 64, 65] and often overestimate time spent in physical activity [66]. In our study, the primary outcome will be step count, which has been shown to be a valid measure of physical activity [67]. Participants will be instructed to wear the ActiGraph accelerometer on their right hip, attached to an elastic belt, all day long for 7 days and to remove it when they go to sleep at night. If wearing time is less than 4 consecutive days, including one weekend day [68], for at least 7 waking hours per day [69], the participant will be excluded from the study. The number of steps measured in the week before and after the intervention, as well as 1, 3, 6, and 12 months after the intervention will be used as the primary outcome. The ActiGraph has shown satisfactory validity and reliability (intraclass correlation = 0.80) [62, 70]. Studies have shown that measures of physical activity using accelerometry in older adults are feasible and provide more valid and reliable data than questionnaires [71, 72, 73].

Secondary Outcomes

The secondary outcomes will allow for the exploration and examination of indirect health effects related to increases in physical activity and decreases in sedentary behaviour. Such exploratory research is important to capture broader effects of the intervention, generate new hypotheses, and guide future interventions.

Reflective and Automatic Processes Underlying Physical Activity : We will assess affective experiences related to physical activity because they are closely related to the perception of effort and could therefore explain the difficulty in engaging in regular physical activity [39].

Explicit Affective Attitudes Toward Physical Activity: Explicit attitudes toward physical activity will be calculated as the mean of two items based on two bipolar semantic differential adjectives on a 7-point scale (unpleasant-pleasant; unenjoyable-enjoyable). The statement begins with "For me, to participate in regular physical activity is …" [74]. The reliability of this measure of explicit attitudes has been validated with a Cronbach's alpha greater than 0.89 [74]. In a recent study of older adults, Cronbach's alpha was 0.92, further supporting the reliability of this measure [36].

Approach-Avoidance Task: A contextual approach-avoidance task will be used to measure automatic approach and avoidance tendencies toward physical activity and sedentary behaviours [26, 36]. Participants will be asked to move a manikin (i.e., an avatar) on the screen "toward" (approach condition) and "away" (avoidance condition) from images depicting physical activity and sedentary behaviours by pressing keys on a keyboard. Each trial will begin with a black fixation cross-presented randomly for 250–750 ms in the centre of the screen with a white background. Then, the manikin will appear in the upper or lower half of the screen. At the same time, a stimulus depicting "movement and active lifestyle" (i.e., physical activity) or "rest and sedentary lifestyle" (i.e., sedentary behaviour) will be presented in the centre of the screen. Participants will be instructed to quickly move the human figure "toward" a stimulus (approach) depicting physical activity or "away" from a stimulus (avoidance) depicting sedentary behaviours, or vice versa. After viewing the manikin in its new position for 500 ms, the screen will be cleared. In case of an incorrect response, an error notification (i.e., a cross) will appear in the centre of the screen. The approach-avoidance task is a reliable and well-validated measure of approach–avoidance tendencies [75, 76]. In terms of validity, this task has shown the most consistent pattern of associations with physical activity outcomes [77]. In addition, this task has shown good reliability (split-half method: r = 0.76) [78].

Physical Effort Scale: The 8-item Physical Effort Scale [79] will be used to capture individual differences in tendencies to approach and avoid physical effort. The relative tendency to approach physical effort will be computed by subtracting the average score for tendency to avoid physical effort from the average score for tendency to approach physical effort [79]. The Physical Effort Scale has shown high internal consistency ($\alpha >$ 0.897) and acceptable test-retest reliability (intraclass correlation > 0.66) [79].

Physical Fitness

6-Minute Walk Test: In this test, the participant is instructed to walk as far as possible for 6 min in a straight 30-m corridor. Standardized encouragement will be provided at each minute. The outcome is the distance walked during the 6 min. The 6-Minute Walk Test requires minimal technical resources [80] and has demonstrated robust test-retest reliability (R ranging from 0.88 to 0.94) and acceptable convergent and construct validity [80, 81]. The minimum clinically important difference is 20 m [81].

Hand Grip Strength: Grip strength will be assessed using a JAMAR dynamometer. Participants will perform the test with their dominant hand in a seated position, shoulder and wrist in a neutral position, elbow flexed at 90º. Two tests will be performed by each participant and the higher value will be recorded as the outcome [82]. This measure has shown acceptable validity and excellent reliability (intraclass correlation coefficient = 0.95) [83]. The minimum clinically important difference is 5 kg [84].

Quality of Life

World Health Organization Quality of Life – Brief Version (WHOQOL-BREF): This scale assesses quality of life in four domains: Physical health (7 items), psychological health (6 items), social relationships (3 items), and environmental health (8 items). Scores for each domain can range from zero to 100, with higher scores indicating better quality of life [85]. Cronbach's

alpha values for the different domains range from 0.66 (for domain 3) to 0.84 (for domain 1), indicating good internal consistency [86]. The minimum clinically important difference of the WHOQOL-BREF for each domain is as follows: Physical = 1.5, psychological = 1.3, social relationships = 1.3, environment = 1.1 [87].

Data Collection and Management

All information will be collected by the research assistant. Each participant will be given a unique confidential identification code at the time they accept to participate in the study. The confidentiality of the information collected will be guaranteed by using this unique confidential code for data storage and analyses. Data will be kept on the University of Ottawa OneDrive account of the principal investigator, with access limited to team members. This system is protected by multi-factor authentication, meets Personal Health Information Protection Act (Ontario, Canada) requirements, and is serviced by the University of Ottawa cybersecurity team. Storage will be maintained for 10 years after the end of the study.

Data Analyses

Primary Analyses: Statistical analyses will be conducted according to the intention-to-treat principle and the Consolidated Standards of Reporting Trials (CONSORT) guidelines. A sequential analysis will be conducted with an interim analysis after 50% of the data is collected and the other analysis after all data is collected [88]. Based on the Pocock boundary, the threshold for significant p-values will be .0294 [89]. If the effect is significant at the interim analysis, thereby indicating that the data provide support for the hypothesis, data collection will be terminated. Mean, standard deviation, median, and range values will be used to summarise the continuous data. The primary outcome (number of steps per week) will be analysed using multiple linear regressions. Specifically, we will test whether the physical activity level (number of steps) of participants in the week after the end of the intervention is higher in the intervention group compared to the comparison group, after adjustment for covariates (i.e., age as a continuous variable, sex). In addition, we will test whether participants' automatic tendency to approach physical activity is higher in the intervention group compared to the comparison group and whether participants' automatic tendency to approach sedentary behaviours is lower.

Secondary Analyses: The continuous outcomes will be analysed using linear mixed-effects models, which account for the nested structure of the data (i.e., multiple observations within a single participant), thereby providing accurate parameter estimates with acceptable type I error rates [90]. To examine the effect of the intervention on the changes in physical activity and sedentary behaviour, models will include interaction terms between group (intervention group vs. comparison group) and number of days within or after (follow-up) the intervention. We will treat the continuous secondary outcomes similarly to the primary outcome. R software will be used for all analyses.

Discussion

Most people are aware of the health benefits of regular physical activity and have good intentions to exercise. Yet, 1.4 billion people worldwide are inactive, suggesting that transforming intention into action can be challenging. Recent findings shows that the intention-action gap could be explained by negative automatic reactions to stimuli associated with sedentary behaviour [21, 22, 23, 24, 25, 26, 27, 28, 29, 30]. This gap is of particular concern in older adults, who are more likely to spontaneously associate physical activity with fear, pain, or discomfort [40]. Current physical activity interventions largely focus on providing rational information to change conscious goals [18]. However, these strategies have been shown to be insufficient in changing behaviours [6, 20]. Therefore, to promote physical activity, the current project proposes to train older adults to counteract their automatic attraction to sedentary stimuli and to respond positively to physical activity stimuli. The intervention is expected to reduce physical inactivity during the intervention and at follow-up. More broadly, the output of this program has the potential to develop an evidence-based, large-scale, and low-cost intervention that would complement current reflective approaches in older adults to improve their quality of life. Finally, the results will inform public health policies aimed at addressing a global health problem: The pandemic of physical inactivity.

Strengths of this protocol include procedures that limit the potential for questionable research practices (i.e., pre-registration, power analysis, pre-printing, data sharing plan) [60]. However, potential limitations should be noted. First, due to the longitudinal nature of our design, we cannot exclude the possibility of selection bias related to attrition. Second, voluntary participation may favour the selection of participants with better health status or higher motivation to engage in physical activity.

Authors' Contribution

Based on the Contributor Roles Taxonomy (CRediT), individual author contributions to this work are as follows:

- Ata Farajzadeh: Writing – Original Draft; Writing – Review and Editing
- Miriam Goubran: Writing – Review and Editing
- Layan Fessler: Writing – Review and Editing
- Boris Cheval: Writing – Review and Editing
- Zack Van Allen: Writing – Review and Editing
- Matthieu P Boisgontier: Conceptualization; Writing – Original Draft; Writing – Review and Editing; Supervision; Project Administration; Funding Acquisition.

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