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Evaluating the implementation process of a new telerehabilitation modality in three rehabilitation settings using the normalization process theory: study protocol

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ABSTRACT

Introducing innovations such as telerehabilitation (TR) into routine care involves complex changes in organizations. This study protocol aims to (1) examine the extent to which a TR platform was implemented as intended in three clinical settings and (2) identify which TR activities were becoming integrated into routine clinical practices, and which factors affect the routine use of the platform. A mixed-method prospective single-case study design with multiple embedded units of analysis will be used. Pre/post-implementation data collection will focus on implementation leaders, clinical champions, upper management, and clinical staff. Qualitative data include semistructured individual interviews with leaders, champions, and upper management as well as focus groups with clinical staff who are users and non-users of the TR platform. Quantitative data include TR use data and TR implementation questionnaires. The consolidated framework for implementation research will be used to analyze the implementation process and normalization process theory will be used to analyze the embedding of TR in routine daily practice. The project is expected to yield evidence regarding which specific TR activities are implemented in day-to-day clinical activities as well as capture threats and opportunities to normalization at a critical moment when it is expected to occur.

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Telerehabilitation; telemedicine; implementation; normalization; knowledge translation; technology adoption; rehabilitation

Background

Telerehabilitation (TR) is increasingly proposed as an alternative or supplementary method for rehabilitation service delivery. TR is encompassed under the often interchangeable terms of eHealth, telemedicine, or telehealth interventions (hereafter referred to as eHealth). However, TR more specifically refers to the provision of rehabilitation services over distance using information and communication technologies. Clinically, it encompasses the full range of rehabilitation services, including assessment, prevention, education, monitoring, consultation, intervention, and counseling. It can include communication between clinicians, patients, and caregivers [1,2]. The use of TR is advocated to minimize barriers of distance, time, cost, and healthcare system load, in order to maximize accessibility to and use of rehabilitation services [3,4].

Among TR technologies, the most widely used and most studied involve bi-directional video conferencing using various devices [4–10] with other studied modalities including virtual and augmented reality devices [8–11] and remote tracking and monitoring devices [12–15]. The existing evidence on the efficacy of TR, although limited, demonstrates that it is a promising option with benefits across several disabilities [3,10]. Systematic reviews validate its use to treat motor function following orthopedic surgery [16], to address symptoms of multiple sclerosis and their impacts on function and quality of life [6], to deliver care following cardiopulmonary diseases [7] and stroke [17], and to provide counseling following spinal cord injury [5]. Regarding stroke rehabilitation, a systematic review of comparative studies also provides limited- and moderate-quality evidence that TR has effects comparable to those of conventional rehabilitation in improving activities of daily living and motor function [8]. A systematic review on TR effectiveness for improving vision-related quality of life is also under way [9]. However, most published reviews stress the low- to moderate-quality of the evidence currently available.

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Despite their anticipated benefits, implementing eHealth modalities in healthcare settings is found to be much more complex and time-consuming than anticipated [18,19]. Indeed, the incorporation of innovations into routine care has been found to involve complex change at the organizational and individual levels [20]. Thus, the sustainable implementation of such innovations has become a recognized problem and a topic of study [21,22]. Indeed, the number of papers published on this topic has risen steadily since 2008 as a result of this recognition [20].

Theoretical frameworks for technology use in health care

Models have been developed within the implementation literature to explain determining factors of the adoption of innovations in healthcare settings [23,24]. However, the literature specifically addressing sustainability remains fragmented, underdeveloped, and mainly based on *post hoc* research [25]. This gap in the literature has led to calls for the development of theory-informed research designs examining the nature of innovations, their potential for adaptation, implementation fidelity, and the influences on their sustainable implementation.

Within the implementation literature, the consolidated framework for implementation research (CFIR) [26] provides an integrative typology of the determinants of implementation which streamlines the terminology and definitions of other models and is designed to guide evaluative work and develop the field of implementation research. In addition, the normalization process theory (NPT) has emerged as a useful framework to characterize the embedding of complex interventions consisting of multiple behavioral, technological, and organizational components into routine daily practice; i.e. their *normalization* [27,28]. NPT is based on the notion that how technology is ultimately used (or *normalized*) is the result of an adoption process taking place in a given context. Thus, normalization is not a static concept: it is achieved over time. NPT attempts to explain this dynamic process by examining four factors which explain what promotes or inhibits the operationalization and embedding of these interventions: coherence, cognitive participation, collective action, and reflexive monitoring. The theory helps to describe how clinicians and other stakeholders' work impacts the implementation process of a technology. The theory is described in detail elsewhere and synthesized on the authors' web site [29]. A summary table with key questions to address within each construct and sub-construct of the framework was developed by Mair et al. [20] which is adapted within the context of this study in Table 1.

A recent qualitative systematic review of studies using NPT found that the constructs of the framework are stable across diverse settings and provide a beneficial heuristic to explain implementation processes [30]. As such, NPT can be a helpful framework to draw lessons from a range of implementation experiences and develop recommendations for healthcare managers wishing to engage in TR implementation efforts in other contexts. The model has been used in over 40 papers [31] to study real-world interventions, such as teledermatology [32], and to understand the experience of implementers of several other eHealth initiatives including electronic record systems [33]. To our knowledge, no study has applied the NPT to examine the implementation of TR.

Methods

Goals of the study

The proposed study aims to examine the adoption of a TR platform in three rehabilitation settings. For this study protocol, routine use is defined as TR being

Table 1. NPT coding framework that will be used for the qualitative analysis of pre/post-implementation interview data (adapted from Mair et al. [20]).

Coherence (sense-making work)	Cognitive participation (relationship work)	Collective action (enacting work)	Reflexive monitoring (appraisal work)
Differentiation Is there a clear understanding of how TR differs from existing practice?	*Enrolment* Do individuals 'buy into' the idea of the TR platform?	*Skill set workability* How does the TR platform affect roles and responsibilities or training needs?	*Reconfiguration* Do individuals try to alter the new TR platform?
Communal specification Do individuals have a shared understanding of the aims, objectives, and expected benefits of the TR platform?	*Activation* Can individuals sustain their involvement in the use of the TR platform?	*Contextual Integration* Is there organizational support for using the TR platform?	*Communal appraisal* How do groups judge the value of the TR platform?
Individual specification Do individuals have a clear understanding of their specific tasks and responsibilities in the implementation of the TR platform?	*Initiation* Are key individuals willing to drive the implementation of the TR platform?	*Interactional workability* Does the TR platform make people's work easier?	*Individual appraisal* How do individuals appraise the effects of the TR platform on them and their work environment?
Internalization Do individuals understand the value, benefits, and importance of the TR platform?	*Legitimation* Do individuals believe it is right for them to be involved in using the TR platform?	*Relational integration* Do individuals have confidence in the new TR platform?	*Systematization* How are benefits or problems of the TR platform identified or measured?

appropriately used as part of day-to-day clinical activities.

Specific research questions

(1) To what extent is the TR platform implemented as intended, in terms of both amount and types of TR activities?
(2) Which TR activities are integrated into routine clinical practices? and
(3) What factors appear to facilitate and hinder the normalization of the TR platform at the level of (a) individual clinicians; (b) clinical teams, and (c) organizations?

Context of the study

TR project planning and implementation

In 2014, an in- and outpatient rehabilitation facility (IORF) and an outpatient rehabilitation center with a focus on social reintegration (ORF) in Montreal (Canada) were providing specialized care, such as rehabilitation and adaptation services including socio-professional reintegration support to patients with acute and/or persistent physical limitations resulting from a variety of conditions (trauma and head injury, stroke, neurological disorders, orthopedic injuries, etc.). Many of the services are provided on an out-patient basis with regular follow-ups. However, traveling to the facilities can be problematic for some clients as many patients resided in a wide geographical area. As well, clinicians can be required to travel into the community, sometimes outside the Montreal area, to provide consultations for patients, thus limiting the availability of already scarce rehabilitation resources. Upper management in each center, therefore, mandated a project leader to develop a common TR pilot project, with TR to be used with patients for whom access to services is a limiting factor for optimal rehabilitation services (e.g. consultation for technical aid with a patient living in a remote area). The project leaders were guided by a local university health network. Specific clinical programs were identified prior to implementation based on a locally conducted patient needs assessment. Clinicians of all disciplines could opt to use TR if they deem it appropriate.

The implementation team estimated that at least 30 patients, some of whom will partake in multiple TR sessions, will have used TR during the initial 12-month implementation period. After this time, TR was expected to become part of the services provided by the centers.

An additional outpatient rehabilitation center for persons with hearing impairments (ORF-H) started implementing the same TR platform in 2015. The three rehabilitation centers are part of a common health network. Implementation at all three facilities was scheduled to take place over a 12-month period starting in January 2015 (IORF, ORF) and January 2016 (ORF-H). Funding for studying the TR implementation process (i.e. the study protocol presented her) was obtained in March 2015 and the project was approved by the Centre for Interdisciplinary Research in Rehabilitation (CRIR) institutions' Research Ethics Board.

The TR platform

The three sites chose the *Remote Education, Augmented Communication, Training, and Supervision* (Reacts) platform to provide TR services. It is a bi-directional video conferencing application designed with strong encryption capabilities to ensure secure connections appropriate for confidential, healthcare-related communications. It allows the sharing of multimedia content during interactions (images, videos, screen captures, files, digital objects, etc.). It also allows multiple video streams, which can enable healthcare professionals to see each other while performing various acts. The platform can be used on computers, notebooks, and tablets and is marketed as reasonably priced, accessible, and specifically designed for use in eHealth services [34]. At the three facilities, the platform is installed on desktop computers located within the offices of several individual clinicians and on shared desktop computers within designated therapy rooms.

Design

The study will use a mixed-method prospective single-case study design with multiple embedded units of analysis. Case studies allow an in-depth understanding of a phenomenon [35], in this case the use of TR within the natural context of the rehabilitation setting. The units of analysis are the three rehabilitation settings where TR will be used.

Frameworks

In this study, the CFIR will be used to analyze the determinants of implementation success and NPT will be used to analyze the determinants specifically related to normalization. The use of both models will allow the consideration of a range of individual, organizational, and contextual factors which may influence TR implementation.

Consolidated framework for implementation research

The CFIR is an integrative framework, which provides structure when assessing complex, interacting, multilevel, and transient implementation determinants. It is based on key constructs from published

implementation theories and was developed both to guide evaluative studies and to help build a more coherent knowledge base within the field of implementation science [26]. The CFIR is composed of five domains (i.e. the intervention, inner and outer setting, the individuals involved (e.g. their knowledge and beliefs), and the process used for implementation) that interact in complex ways to influence implementation of innovations and integration into clinical routines. These domains can all be conceptualized as determinants of the successful implementation of innovations.

Normalization process theory

The NPT was developed to help understand the processes that lead to implementation of innovative health technologies, including telemedicine [27]. NPT is an action theory; therefore, it is concerned with the actions individuals take (e.g. using TR) and it can help to explain the social processes leading to the routine use of an innovative health technology. NPT helps to understand how clinicians impact the normalization process of a technology.

The two frameworks were used to inform the design of data collection tools (see procedures section) and will be used for data analysis.

Procedures

The study methodology is based on best practices for mixed methods research in health sciences [36]. It primarily uses a qualitative core, supplemented by a quantitative component, with multiple data sources.

Informants regarding the TR adoption process will include implementation leaders (one per site, $n = 3$); clinical champions (one per site, $n = 3$); clinical staff who are part of the clinical programs where TR may be used (approximately $n = 200$) and upper management stakeholders at each site (minimum one per site).

Qualitative data sources

Qualitative data will be collected through official implementation project documents, interviews, and focus groups.

(1) *Project documents*. Documents produced by the implementation team, including implementation plans and meetings minutes, will be reviewed to identify factors that may have impacted on the implementation process at each site, as well as to compare the intended implementation process with actual implementation.
(2) *Pre-implementation semistructured individual interviews* (30–45 minutes). The project leaders at each site ($n = 3$) will be interviewed during the early stages of the implementation process (i.e. first 6 months post-onset). Semistructured interview guides will aim to elicit details on the perceived level of complexity of the TR implementation project, intended use of the TR platform, the implementation protocol, and the anticipated facilitators and barriers to the project.
(3) *Post-implementation semistructured individual interviews* (30–45 minutes) will be conducted at the end of the intended implementation period (approximately 12–18 months post-onset). Interviews will be conducted with the project leaders, clinical champions, and representatives of upper management involved in the initial decision-making process at each site. Questions will aim to elicit perceptions on the fidelity of project activities as compared to the initial implementation protocol (i.e. to what extent was TR implemented as intended), current uses of TR by clinicians and facilitators and barriers to normalization [25].
(4) *Post-implementation focus groups* (60 minutes) will also be conducted at the end of the intended implementation period with two separate groups of (a) users with different levels of experience with the new TR platform and (b) non-users of the platform who have not used it during the implementation period. Each group will involve $n = 2–3$ clinical staff members from the three facilities, for a total of 6–9 participants per group. Questions will be based on NPT, informed by previous individual interviews and questionnaires (see quantitative data below) and will aim to understand how TR was used by clinicians, and the extent to which TR activities are integrated (or not) into clinical routines, as well as to identify facilitators and barriers to the normalization of TR.

Quantitative data sources

Quantitative data will be collected through official implementation documents, web-based questionnaires, and telephone interviews.

(1) *Implementation documents*. Data regarding use of TR by clinicians will be collected monthly (e.g. frequency of TR use by clinician, proportion of clinicians using TR, type of TR activity (e.g. consultation, follow-up, intervention), clinical discipline(s) involved, location of TR (e.g. home service, healthcare institution), clinician, and patient satisfaction). These will be collected by the implementation team in close collaboration with the research team.
(2) *Stages of implementation completion (SIC) questionnaire*. The SIC [37] documents the attainment time for 31 observable implementation milestones and helps identify steps that were not accomplished. It notably documents the date when an organization starts examining the feasibility of an

implementation project, when it formally commits resources to it, when it hires coordinators, and when staff training is completed. The instrument categorizes these stages into three phases of implementation: Pre-Implementation, Implementation, and Sustainability. A 19-item adapted version that includes only milestones applicable to this project was prepared, translated, and back-translated to ensure accuracy. The order in which the centers move through each stage and the number of stages attained will be documented. The questionnaire will be completed through a telephone interview with each facility's implementation coordinator.

(3) *Questionnaires.* Questionnaires for clinician and managers will be administered pre- and post-implementation to obtain perceptions on TR from the clinical stakeholder groups including project leads and clinical champions. A web platform installed on secure servers will be used (Lime survey).
   a. *Technology Adoption Readiness Scale (TARS).* All clinicians in the participating clinical programs (approximately $n = 200$) will be invited to complete a French adaptation of the TARS [21]. The scale contains 30 items scored on a 7-point Likert-type scale. Clinicians score their perception with regard to the presence of factors shown to impact implementation (as proposed by the NPT) and the extent to which the practice has become, and is likely to become, routine practice at their center. The TARS will be administered during the early stages of the implementation process and again at the end of the pilot period. Thirty items are scored on a 7-point Likert-type scale. This instrument has been shown to have good face validity and potential predictive validity by its authors. Additional questions on comfort level with new technologies and normalization were included.
   b. *Organizational Telehealth Readiness Assessment (OTRA).* Program managers, project leaders, and clinical champions ($n = 20$) in the three centers will complete the OTRA early in the implementation period and again at the end of the implementation period. This telehealth-specific questionnaire [38] rates managers' perceptions of organizational readiness, workplace and technology readiness, and organizational planning (considered components of the implementation climate, as defined within the CFIR). Twenty-eight items are scored on a 5-point Likert-type scale, with scores summed for subscores and a total score out of 140. The Canadian French version of this instrument was shown to have good validity [38].

Data analysis

The SIC data will be used to describe which implementation stages were completed and how much time each site spent between each phase (Pre-Implementation, Implementation, and Sustainability). Interview and focus group recordings will be transcribed verbatim. Qualitative data will be analyzed using qualitative data analysis software program (e.g. NVivo 11). Coding schemes derived from the CFIR and NPT will be developed by the research team to synthesize the data. A thematic analysis will then be conducted, whereby themes emerging from the data will be identified, and analyzed first for each site, and then compared between sites [39] and classified within the CFIR and NPT construct. Implementation documents may supplement focus group and interview data.

Quantitative data will be analyzed using the SPSS statistical software package. Pre/post-questionnaires will be paired to allow for longitudinal analyses. Descriptive statistics (frequencies and frequency distributions of different TR activities) will summarize how TR was used on a monthly basis in each site. The *TARS* will be analyzed (based on the NPT) using descriptive statistics for individual items at T1 and T2 (e.g. frequency distributions of scores and change of scores) and Chi-square analysis will be conducted to identify items that relate to lower or higher perceived routine use at each site [21]. Descriptive statistics (means, standard deviation) will be used for the items, subscores, and total score on the *OTRA* at T1 and T2. Subscores and scores will be compared over time and between sites using a mixed-models approach with repeated measures. There is currently little information about sample size requirements for these tools. The research team will work closely with the implementation team to maximize response rates. Results from this study will provide data regarding expected effect sizes for sample size calculations in future studies.

Discussion and conclusion

To our knowledge, this is the first study that will use NPT to examine determinants of TR implementation into routine practices in rehabilitation settings. Furthermore, this study will examine the implementation and normalization at once. For those reasons, the study is expected to yield evidence regarding those TR activities which are becoming normalized as well as capture threats and opportunities at a critical moment when normalization is expected to occur. The context of the implementation is important to document. The three facilities offer programs and

services that are very different in nature and may not implement TR at the exact same pace. This difference may result in different time intervals between data collection points. As well, experiences between facilities may be very facility-specific and a large-scale healthcare reform taking place in the province of Quebec during the implementation period may have impact on each organization differently. These healthcare reforms were unforeseen and are being implemented as the TR implementation is taking place, which could impact their outcome and will be important to document.

This will also set the stage for a more long-term study which will examine the normalization of TR use 24–36 months post-implementation, as recommended by authors such as Wiltsey-Stirman et al. [25] Since some components of innovations may be maintained over time, while others are abandoned, it is currently recommended to assess sustainability over several years rather than at a single time [25].

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Disclosure statement

No potential conflict of interest was reported by the authors.

Ethics approval: Ethics approval for this study was obtained from the institutional review board of the Center for Interdisciplinary Research in Rehabilitation of Greater Montreal for all participating facilities (certificate number CRIR-1074-04-15). Consent to participate will be obtained from all informants during the course of the study.

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