

**PROTOCOL**

# The Effect of Text Message-based Support Program (TextRehab) on Treatment Outcomes of Patients with Hand Flexor Tendon Injuries after Repair: A Randomized Controlled Trial Study Protocol

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*Research performed at Mashhad University of Medical Sciences, Mashhad, Iran*

*Received: 01 May 2021*

*Accepted: 10 September 2021*

**Abstract**

**Background:** Post-operative rehabilitation for patients with flexor tendon injuries is necessary for a full recovery. This randomized controlled trial study investigates the effectiveness of a text message-based rehabilitation program (i.e., TextRehab) on the improvement rate of hand rehabilitation in patients with flexor tendon injuries after repair.

**Methods:** This study is designed as a randomized, three-month, single-center, two-arm, parallel controlled trial. A total of 40 patients will be randomly classified as either the control or intervention group. Both groups receive usual care; however, the intervention group is also asked to perform the designed rehabilitation activities through the TextRehab program. The activity instructions are sent to patients step by step at least once a day. Self-reported outcomes will be assessed at 6 and 12 weeks after discharge and include self-reported Patient Rated Wrist Evaluation, self-reported Quick-Disability of Arm, Shoulder, and Hand, and Visual Analogue Scale. Moreover, the reports of the physician regarding the grip strength and Total Active Motion will be assessed at week 12.

**Results:** The development of the message scheduling system and its contents is completed. This trial has the code of ethics in research (IR.MUMS.fm.REC.1396.247). Study results are expected to be available in mid-2021.

**Conclusion:** The TextRehab program is developed to provide advice, motivation, information, and care for patients with hand flexor tendon injuries after repair. This trial provides evidence of the effectiveness of sending text messages on persuading patients to perform home-based rehabilitation activities.

**Level of evidence:** Not applicable

**Keywords:** Flexor tendon injury, Home-based rehabilitation orthopedic, mHealth, Text message

**Introduction**

Most patients with flexor tendon injuries suffer from a limited range of motion, formation of adhesions, insufficient strengthening of muscles, and loss of functionality in their hands or fingers (1). Early mobility after surgery has been shown to improve hand

functionality and prevent adhesion formation, stiffness, and deformity (2). The results of studies have also shown that post-operative rehabilitation programs improve the outcomes of hand functionality in patients with flexor tendon injuries (2-4). Adherence to physiotherapy

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programs, especially home exercise programs, can be low among patients due to either forgetting their exercise schedule or being exposed to pain during exercise (5). On the other hand, self-managed exercise is an attractive solution for home-based rehabilitation, especially when it is not possible to continue with outpatient rehabilitation (6).

Mobile Health (mHealth) is the use of mobile communication technologies, including mobile/cell phones using cellular networks, to improve health outcomes, healthcare services, and health research (7). Cell phone interventions enable patients and physiotherapists to reduce or eliminate barriers to physical exercises, such as transportation, financial cost, inadequate time, and bad weather conditions; therefore, such interventions increase adherence to a health management program (8). Text messaging is more practical due to the wider accessibility of people to mobile phones with short message service (SMS) than smartphones (9). There is a growing body of research supporting the use of text message-based interventional systems and instructional videos for increasing physical activities and self-managed exercises (10-16).

This study introduces the TextRehab program, and details the research protocol of a trial to determine the effectiveness of instructional videos and text messages delivered via TextRehab on improving patients' adherence to physical therapy (home-based rehabilitation) along with their usual care. This study hypothesizes that patients whose flexor tendon injuries have been repaired will perform post-operative home-rehabilitation programs more easily by using mobile phone intervention as a tool to increase self-care adherence. To the best of our knowledge, up to now, there has been no published study on the effect of text message-based self-care (home-based rehabilitation) interventions on patients with flexor tendon injuries.

## Materials and Methods

### 2.1. Study Design

This protocol describes a randomized, three-month, single-center, two-arm, parallel controlled trial to evaluate the effectiveness of a text message-based rehabilitation program (TextRehab) on primary and secondary outcomes, which will be assessed at 6 and 12 weeks from baseline. This protocol is conducted in accord with the Standard Protocol Items: Recommendations for Interventional Trials 2013 statement (17), and the intervention is described according to the Consolidated Standards of Reporting Trials of Electronic and Mobile EHealth Applications and onLine TeleHealth checklist (18, 19).

The duration of the study is expected to be 16 months, which includes needs assessment, content development, TextRehab web-based management system development, participant recruitment, randomization, intervention allocation, intervention delivery, follow-up, and data analysis. The trial will be run for 12 weeks for each patient.

### 2.2. Randomization and allocation concealment

This study is designed as a randomized controlled trial. After the confirmation of eligibility, 40 participants will be randomized in a 1:1 ratio to either the intervention group (usual care plus the 90-day text messaging program) or the control group (usual care), using an online random number generator (randomization.com). A member of the research team will conceal the assignment of subjects to each group in sequentially numbered opaque, sealed envelopes.

### 2.3. Blinding and consenting

Due to the nature of the intervention, patients cannot be blinded; however, participants will not be aware that there are two research groups. The intervention applicator must know about the assignment details, after they are revealed, to manage to send text messages to participants in the intervention group.

The study coordinator performing the recruitment will be blinded until the patient has consented to participate. Written informed consent will be obtained from each eligible patient before entering the trial. After obtaining consent, the study coordinator begins to distribute the envelopes that encode patients to either the intervention or control group, which is performed by giving each patient the top envelope from the prepared stack of sealed envelopes.

Physicians who visit patients and physiotherapists who provide rehabilitation to participants are blinded to the allocation. Professional academic biostatisticians blinded to study groups will conduct all analyses.

### 2.4. Ethics approval

This trial has the code of ethics in research (IR.MUMS.fm.REC.1396.247).

### 2.5. Baseline measurement

After obtaining informed consent, at the baseline, information such as age, gender, education, marital status, affected side, smoking status, comorbidities, and past medical history will be collected.

### 2.6. Participants and setting

Hand surgeons will screen the patients who have undergone hand flexor tendon repair surgery at a level three academic hospital for clinical eligibility. Those who meet the eligibility criteria will be screened for the considerations of inclusion criteria by the principal investigator. Subsequently, the final patients will be recruited for this study. Inclusion criteria are adult patients having a hand and finger flexor tendon injury and having undergone repair; being over 18 years old, possessing a cell phone, being fully willing to participate in the study, and being able and willing to give informed consent. On the other hand, patients will be excluded if they have neurological or psychiatric diseases that would result in an inability to interact with a cell phone, are medically unstable, are unable to participate in the exercise program, or have any previous hand deformity, injury, or dysfunction. Moreover, they will be excluded if they have a concomitant hand or finger fracture, extensor

tendon injury, or treatment interval of more than 2 weeks. Information about the study will be provided to patients after the surgery and before discharge. A designated phone number will be given to patients that can be contacted if they need help. Patients will be assessed at weeks 6 and 12 after discharge, and the analysis outcomes will be compared. A flow diagram of

the trial's progression (i.e., recruitment, randomization, intervention allocation, follow-up, and data analysis) is shown in Figure 1.

**2.7. System development (TextRehab)**

The following phases will be used to design and develop the TextRehab system:

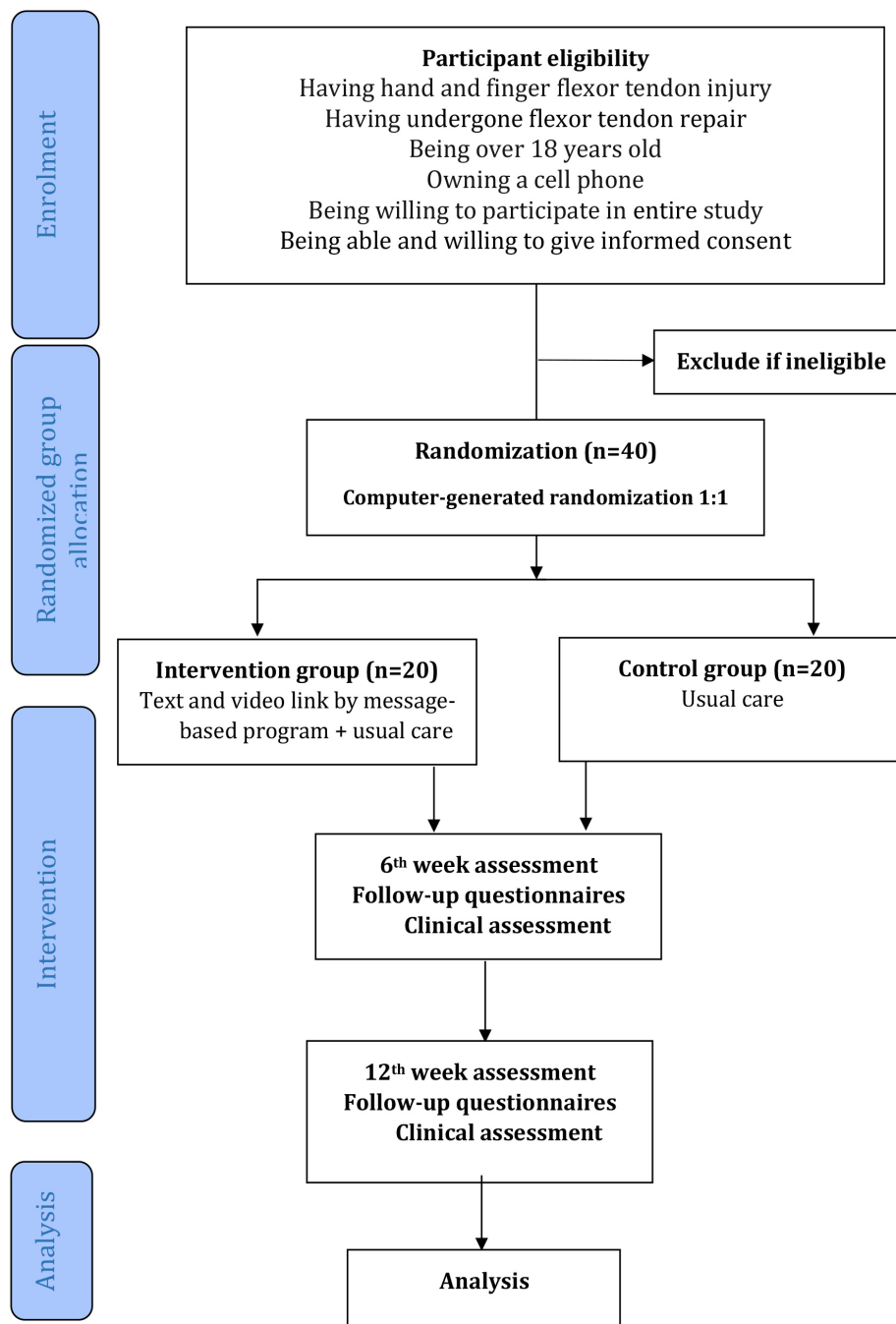


Figure 1. Flow diagram of the trial's progression.

### 2.7.1. Phase 1: Needs assessment

At first, a field survey will be conducted to obtain a general overview of patients' needs for information. For this purpose, one of the study researchers will take part in patients' visit sessions held by orthopedic specialists at a university orthopedic center for 1 month. Furthermore, by searching the scientific texts, articles, and rehabilitation protocols available in medical centers worldwide and consulting with two hand subspecialist surgeons, patients' needs were identified in terms of their health problems, activity constraints, criteria for preventing recurrence, financial resources, future referrals, pain and its management, activity onset, and recovery period for patients with flexor tendon injuries in each of the 5 flexor zones of the hand. Additionally, the follow-up process of patients with flexor tendon injuries was investigated after discharge.

### 2.7.2. Phase 2: content development

To prepare the rehabilitation instructional content, Duran therapeutic protocol suggested by specialists was used (20). This therapeutic protocol was specifically designed for patients suffering from hand flexor tendon injuries. Moreover, to be noted is that rehabilitation treatment is commonly recommended to patients at the center under study. Instructional content is then prepared in two formats, including text message and video, which are described in detail below.

#### • Text messages

The purpose of text messages is to provide advice, motivation, information, and care. The messages are carefully designed in order to persuade patients to perform home-based rehabilitation exercises, using a specific therapeutic protocol for rehabilitation exercises of patients with hand tendon injuries. The content of messages was produced and edited, using a number of techniques recommended in behavioral change theories, which are known to be useful for persuading patients to perform specific behaviors.

A total of 104 text messages are developed based on a flexor tendon rehabilitation protocol (Duran), which is an early passive mobilization that can help yield excellent results.

Four groups of messages are developed, including:

- Dressing, wound care, duration of the splint wear, and bathing;
- Pain management;
- Follow-up appointments; and
- Rehabilitation exercise messages.

All messages are understandable for patients with any level of education and contain a link to the website.

After preparing the messages, the content is reviewed, edited, and approved by orthopedic super specialists and medical informatics specialists.

#### • Instructional videos based on corresponding text messages

Instructional videos are prepared in accordance with each treatment stage and with regard to the text messages.



Figure 2. Screenshot of rehabilitation instructional videos.

Rehabilitation instructional videos are prepared with the help of hand surgeons for patients with flexor tendon injuries. An actual patient helps us with the recordings, and the videos are made according to treatment stages [Figure 2].

There is a link to the corresponding video at the end of all rehabilitation exercise text messages (URL links that direct patients to the website where rehabilitation videos are uploaded). Such multimodal content acts as a complementary resource for the better understanding of rehabilitation activities in addition to what can be provided in a text message.

### 2.7.3. Phase 3: Design and development of message scheduling system

The text message-based intervention will be delivered by our designed TextRehab web-based management system. This text message system delivers daily text messages. The information of participants randomized to the intervention group, including their characteristics, will be registered through our text messaging web-based management system. The program runs a series of background checks to ensure data accuracy. A log of all transactions with participants, including seen videos, time of sending messages, and delivery reports, is retained. After uploading the instructional videos on the website, it is possible for the research team to monitor the number of times the links are accessed.

To transfer and schedule the necessary recommendations from the physician to the patient in an effective way, various packages with different subjects can be defined on the website that can then be sent to patients at flexible times [Figure 3]. It should be mentioned though that the package sent to the study population will only be one specified package. Since the content of messages is already defined in each package, it is possible to deliver them in the form of SMS in a long interval of time which then allows for the completion of rehabilitation training.

The patients' follow-up system was designed and analyzed based on the patients' needs and with the help of a computer, medical informatics, and hand surgery specialists. This system was created with ASP.Net language using a visual studio as the web application. MySQL was also used to manage the databases.

### 2.8. Usual care

The control group will only receive appointment reminder text messages a day before their appointments.

Package	Group	edit	delete	scheduling
Recommendations before surgery	Patients with total knee replacement			
home-based rehabilitation exercises	Patients with flexor tendon injury			
duration of the splint wear and bathing	Patients with flexor tendon injury			
appointments	Patients with flexor tendon injury			
physiotherapy	Patients with flexor tendon injury			
Self-Care	Patients with total knee replacement			
Usual Recommendations after surgery	Patients with flexor tendon injury			
Radiography	Patients with flexor tendon injury			
Dressing and Wound Care	Patients with flexor tendon injury			
Reminders	Patients with flexor tendon injury			

Figure 3. Screenshot of the package creation page.

Reminders contain the patient's name, location, clinic name, and date and time of the upcoming visit. The patients in this group will receive the usual care provided to all patients with flexor tendon injury after surgery, which might include rehabilitation as recommended by their hand surgeons if necessary.

### 2.9. Intervention

Participants in the intervention group will receive text messages about post-operative care for 12 weeks and appointment reminder text messages a day before their appointments at no cost. The text messaging program will begin the day after the participant's discharge from the hospital. The messaging intervention will be provided in addition to usual care provided to all patients with flexor tendon injury after surgery, which includes rehabilitation as recommended by their hand surgeons.

The content of the message will act as both a reminder and a cue to action. The content will change based on the Duran rehabilitation protocol throughout the study. At least one message will be sent per day, and the participants can choose when to receive messages throughout the day. Before the start of the intervention, a test message will be sent to each patient to confirm their phone numbers and check whether the system is working well. If patients do not receive messages, the intervention applicator will update the correct phone number. Participants are expected to use the messages for 12 weeks daily. Approximately 80% of messages contain links to the videos related to their content. A patient participating in the full 12-weeks intervention will receive a total of 104 messages. Participants are able to request to stop receiving the text messages by calling the intervention applicator.

### 2.10. Outcome measures

Self-reported outcome measures will be collected at two temporal points, namely 6 and 12 weeks post-operatively.

### Primary outcome

The primary outcome measure is a 15-item self-reported questionnaire that will be used for rating wrist-related pain and disability in functional activities as measured by a translated version of the Patient Rated Wrist Evaluation (PRWE) (21). Each item is scored from 0 to 10. The score consists of two domains, including the pain domain (n=5 items) and the function domain (n=10 items). The total functionality score on the PRWE scale ranges from 0 (normal wrist) to 150 (complete disability) (22).

### Secondary outcomes

**Quick Disabilities of Arm, Shoulder, and Hand Score:** A translated version of this questionnaire is used as a self-reported survey of function and symptoms in patients with upper extremity disorders (23). This 11-item tool assesses the ability to perform physical activities (n=8 items) and pain (n=2 items), and 1 item is related to sleep. Each item is scored on a 5-point Likert scale (from 1=least difficult or severe to 5=most difficult or severe), with a lower score indicating a better outcome (24).

**Visual Analog Scale:** Patients will be asked to fill out the 10-point Visual Analog Scale which questions the average pain level during the past 7 days. The total score of this tool ranges from 0 (no pain) to 10 (extreme pain) (25).

**GRIP strength:** The handgrip strength will be measured using a hydraulic hand dynamometer (SAEHAN Corporation, Masan-Korea) for both the injured and uninjured hands while the lower arm is resting on a flat surface and the elbow flexion is at a 90-degree angle. The total active motion (TAM) is calculated with the use of a goniometer at 12 weeks by the outcome assessor. A mean value from injured fingers is measured in patients with multiple finger injuries. The sum of flexion at the metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints in attempt fist position minus the sum of extension at these joints is used to compute TAM (26). Grip strength and TAM will be

evaluated 12 weeks after the discharge.

### 2.11. Sample size

Sample size calculations are based on the primary outcome of wrist function and wrist score (i.e. PRWE score). Moreover, an alpha error is assumed at 0.05, and the percentage of loss at follow-up is considered at 25%. Therefore, the final sample size is determined at 40 participants in order to provide 90% power to detect a difference of 10 points in the PRWE score, which is considered to be clinically relevant in this study.

### 2.12. Statistical analysis

All analyses will be performed based on an intention-to-treat method. Professional academic biostatisticians blinded to group allocation will analyze the data. The collected data will be analyzed in IBM SPSS Statistics 23.0. All analyses will be performed using two-sided *P-values* considered significant when below 0.05. The normality of the variables will be assessed using the Kolmogorov-Smirnov test. To demonstrate equivalency between groups, patient characteristics will be compared at the baseline using independent samples t-test for continuous variables (i.e., age and levels of education) and a Fisher's exact test or Chi-square test for categorical variables (i.e., smoking status, marital status, gender, affected side, level of injury [zone II to V]) as appropriate. Mann-Whitney U tests will be used where data are not normally distributed. Differences between primary and secondary outcomes in groups will be tested by independent samples t-test. Differences in the mean of primary outcome scores and secondary outcomes scores between 6 and 12 weeks will be assessed with the paired-samples t-tests. Where assumptions for parametric analysis have not been fulfilled, a non-parametric analysis will be replaced to make these comparisons.

## Results

The study protocol has the code of ethics in research. The development of the message scheduling system is complete. Study results are expected to be available in mid-2021.

## Discussion

This paper describes the protocol of a TextRehab trial designed to evaluate the effect of instructional text messages and videos as a home-based rehabilitation program compared to usual care. This type of intervention can provide self-care support within the intervals between the clinic visits for patients who are discharged from the hospital and live in areas far from the rehabilitation centers.

The findings of different studies have shown that after receiving textual messages, medication adherence has increased in patients with chronic diseases (27-29). Similarly, text messages have been able to effectively increase outpatients' attendance in healthcare centers (30). In addition, based on the results of studies, text messages have been able to improve physical activities in the elderly (10, 31, 32). This trial is also expected to help facilitate the process of communicating and reminding physicians' advice to patients within the

intervals between the appointments. Moreover, early implementation and continuation of an uninterrupted care program will lead to full recovery and rehabilitation of patients, which in turn allows for a faster return to their normal routines.

The designed intervention of this study is prepared by a multidisciplinary team based on the rehabilitation protocols specific for patients with flexor tendon injuries. It is not possible to determine which component(s) of the TextRehab intervention are more effective for improving patients' hand functionality outcomes. However, if effective, this trial will be the first interventional study that demonstrates the effect of mHealth in the improvement of treatment outcomes in patients with flexor tendon injuries in a randomized controlled trial. The effectiveness of the TextRehab intervention, depending on patients' active participation, is potentially applicable to other populations. Another advantage of this study is related to the message delivering process that was designed as a one-way communication; therefore, the intervention is more practical and cost-effective for patients.

Finally, this trial may contribute to the literature regarding the use of mobile phone technology for improving health outcomes in all settings, especially low-resource ones.

**Disclosure:** The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

**Financial support:** This study was supported by the Mashhad University of Medical Sciences Research under grant number 960277. Saeid Eslami Hasan Abadi received the grant.

## Acknowledgments

We would like to thank clinical research development center of Ghaem hospital for their assistance in performing this study.

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