The Effectiveness and Safety of Smartphone for Rehabilitation after Lumbar Spinal Operation: A Multi-center, Prospective, Randomized Controlled Trial

Abstract

Background:

Rehabilitation is very important for postoperative patients with low back pain. However, the promotion of traditional clinic-based program is limited in developing countries like China, due to the maldistribution of medical resources. Smartphones may be a potential substitute for those who have no access to traditional rehabilitation.

Objective:

The aim of this study was to examine the efficacy of a smartphone based rehabilitation system in patients accepted lumbar spinal operation.

Methods:

Postoperative patients with low back pain were recruited and randomized to rehabilitation treatment provide by smartphone based e-health program (EH) or usual care treatment (UC) as control group. Primary outcomes were function and pain status assessed by Oswestry Disability Index (ODI) and visual analogue scale (VAS). Secondary outcomes were general mental health and life status (Likert scales, EQ-5D and SF-36). All the patients were assessed pre-operatively and then at 3, 6, 12 and 24 months post-operatively.

Results

A total of 168 of the 863 eligible patients were included and randomized in this study. The analysis showed that the improvement in EH group was superior to UC group at 24 months postoperatively (mean difference: ODI 7.02, SD 3.1, P<0.05; VAS 7.59, SD 3.42, P<0.05). No significant difference of primary outcomes was found at the other time points. Subgroup analysis showed that the improvements of the primary outcomes were more significant in those considered as high compliance in the EH group throughout the trial, compared with the UC group at 6, 12 and 24 months.

Conclusion:

This research demonstrated that E-health, a smart phone based tele-rehabilitation system can be an effective rehabilitation tool in self-management for postoperative patient with low back pain. The effectiveness of E-health was more evident in high adherent participants. Still, more researches are needed to understand factors associated with patients’ adherence.
Introduction

Low back pain (LBP) is a common health problem with a point prevalence of 15% and a lifetime incidence as high as 85%. LBP is related to disability, work loss and also accounts for high economical costs in societies. Total annual back pain–related costs in the United States exceed $200 billion and still growing [1, 2].

Surgical therapy is an important treatment for LBP [3]. Due to the rapidly aging population, the lumbar spinal surgeries have increased rapidly. However, functional improvement and patient satisfaction are varied; 25% of the patients undergone interbody fusion still suffer from back pain or thigh pain [4, 5]. For those undergone discectomies, 40% are unsatisfied with the operation and the recurrent rate can reach as high as 12% [6].

Recent evidence suggests that patients with lower back pain usually have muscle dysfunction, which may be exacerbated by surgeries. Thus, post-operative rehabilitation becomes very important [7, 8]. Abbott et al suggested that if the patients carried out post-operative rehabilitation 3 months after interbody infusion, their outcome would be superior to those without any rehabilitation program [9]. A systemic review also indicated that postoperative rehabilitation would contribute to a rapid functional recovery and pain alleviation of patients after lumbar spinal surgery [10]. It is also well accepted that, to be effective, patients have to remain adherent to their rehabilitation program [11, 12]. However, there are few efficient and effective strategies to help patients maintain active in rehabilitation therapy. Meanwhile we need to notice that most of the recommended rehabilitation programs are clinic-based, in which patients have to visit the clinics 8 to 12 times. And it makes these programs especially unsuitable for patients in developing countries like China, where patients have to travel a long way to receive their treatments due to the maldistribution of medical resource [13].

The rapid development of smartphone-based programs provides a new option to promote health and to prevent diseases [14-16]. Quinn et al used a smartphone-based software to provide the behavioral therapy of type II diabetes mellitus [14]. Other studies also have proved that the Internet can be successful to promote weight loss [17], increase physical activity [18], and improve self-management behaviors [19].
Thus, we conducted this trial to investigate whether a smartphone-based program, designed to provide tele-rehabilitation for patients with LBP would reduce pain-related disability and improve prognosis among postoperative patients who have no access to traditional clinic-based rehabilitation.

Methods/Design

Trial Design

This study was a multi-center, prospective, randomized controlled trial with patients stratified by surgeon, operative procedures and preoperative diagnosis. This trial was approved by Ethics Committees of Sun Yat-sen Memorial Hospital, with site approval for three hospitals in Guangzhou. Selection bias was avoided by concealing allocation during recruitment. All patients were assessed for functional ability, pain and general mental and health status at baseline and 3, 6, 12 and 24 months post-operatively.

Inclusion and exclusion criteria

The researchers were required to explain the purposes, procedures and possible risk of the trial in detail to the patients before inclusion. Written informed consents were obtained from all patients.

Patients must meet all of the following criteria to be recruited for the study:

1. Aged between 18 and 64;
2. Agreed to receive lumbar spinal surgery and the surgical intervention involved no more than 3 columns;
3. Diagnosed as lumbar disc herniation, spinal stenosis or lumbar spondylolisthesis with imaging support;
4. Patients living at least 100km or 2 hours’ drive away from the hospitals;
5. Signed informed consent.

Sample size

Based on previous studies, we anticipate that to have a 90% chance of detecting a between-group difference of 8 points on the ODI and declaring it statistically significant using a two-sided alpha= 0.05, an enrollment of 168 patients was required. This calculation allowed for loss to follow-up of 23% [11].

Randomization

After completing the baseline survey, each participant was randomly allocated in a 1:1 ratio to the intervention or usual care group by a random number generator. An email was sent to participants to inform them about their group assignment conducted by a central administrator (Hou).
Intervention

Surgical intervention

Spinal surgeries were conducted according to their surgeon’s routine practice for the patient’s condition (i.e. root decompression or discectomy). The details of the preoperative diagnosis and surgical procedures performed were recorded as potential determinants of outcomes.

Usual care

No specific rehabilitation program was provided to patients randomized to the usual care control group. The relevant surgeons’ usual practice was still provided, including advises to keep physically active, analgesia and other symptomatic treatments. And all the post-operative regimes were documented.

Design of e-Health and rehabilitation exercises

Besides relevant surgeons’ usual practice, patients randomized to the intervention group received tele-rehabilitation provided by e-Health, a smartphone-based system developed by our group.

e-Health, designed based on the user-centered theory, aimed to provide a platform for the delivery of self-management interventions [20, 21]. It contained two interfaces: smartphone-based interface and web-based interface. Through smartphone-based interface, patients were able to view the rehabilitation plans made by their physicians and conduct their rehabilitation following the video instructions. Also, users received daily reports about their exercise and an alert to prompt them to return to this system. They could also communicate with doctors through this system. Through web-based interface, the doctors could adjust rehabilitation plans for patients and view reports about their daily exercise. All data was synchronized and stored in a remote server. The e-Health system diagram was presented in figure 1.

The exercises included in this software were designed based on core stability exercise principles, which were all aimed to restore normal muscle strength and mobility, to activate the deep core musculature and to promote balance and coordination of their daily movements

The software was installed into patients’ phones at 3 months after the surgery. Two meetings were hold to show the patients how to use this software and how to conduct these exercises. Patients were also evaluated to make sure they can conduct the rehabilitation exercise correctly. Patients were required to complete at least 2 months of training. After 2 months, patients could still log on to the system. And those who completed 5 or more training each week were considered as high adherence, 3~5 times as medium, 2 times and less as low.
Outcome measures

Primary outcome measures

The primary outcome measures were the Oswestry Disability Index, a disease-specific patient completed questionnaire documenting function of known validity and reliability, and the visual analogue scales (VAS) to record back pain.

Secondary outcome measures

The study was complemented by a series of secondary outcome measures about the mental health, life status, which included: EQ-5D health questionnaire and SF-36 (the MOS item short from health survey) [22, 23].

At 12 months postoperatively, we conducted an open survey of the patients in order to detect the factors that affect patient compliance. All patients with medium and low compliance were asked to list three of the most important factors they thought affecting their compliance to the system.

All the data were collected through face to face assessments conducted in the hospitals where the patients got their surgeries.

Statistical Methods

The analyst assessing trial outcomes was blinded to the assignments. All analyses were conducted using an intent-to-treat approach with participants analyzed according to original group assignment. The baseline data for those lost to follow-up were included. Baseline characteristics were compared between groups using chi-square tests or for categorical data, and two-sample t test for continuous data. Numeric data are represented by mean value ± standard deviation (SD).

For analyses of primary and secondary outcomes, paired t test was applied to examine changes within groups. And two-sample t test was applied to compare changes between groups. Missing data were not imputed. Only the available data were analyzed.

All the analyses were conducted using Stata 23.0. And a $P$ value<0.05 was declared as significant.

Results

Study population and follow-up

Recruitment occurred between August 2013 and November 2014 at three hospitals and 845 patients
were assessed of eligibility; 428 patients were excluded for not meeting inclusion criteria or meeting the exclusion criteria. Of the 417 eligible patients, 92 were not approached. 135 declined to participate. And 22 consented patients withdrawn prior to randomization. At last 168 were randomized in this study.

All the randomized patients received operation treatments and finished the baseline assessments. 2 and 4 patients dropped out in EH group and UC group at 3 months. Thus 82 patients in EH group entered the treatment phase, of which 77 finished the treatment and were met at 6 months. While in UC group, 80 and 74 patients were met at 3 months and 6 months, respectively. Follow-up rate in EH group was 97.6% at 3 months, 91.7% at 6 months, 85.7% at 12 months, 71.4% at 24 months. And in UC group, follow-up rate was 95.2% at 3 months, 88.1% at 6 months, 83.3% at 12 months, 72.6% at 24 months. (Fig 2)

Baseline characteristics
Both the clinical and demographic characteristics of the patients were similar in the two groups (table 1). Most study participants were married and had only finished high school or lower. And on average, participants reported moderate to severe pain and functional impairment.

Adherence to Interventions and possible influence factors
50, 37 and 38 patients were considered as high compliance at 6, 12 and 24 months postoperatively. 22 of them completed the whole trial and were considered as high compliance at all the following ups. Thus, the high compliance rate was higher at 24 months (63.33%) compared with that at 12 months postoperatively (51.39%). But this was not statistically significant ($P = .17$).

At 12 months postoperatively, all patients with low compliance were asked to list three factors they thought that affected their adherence the most. 33 out of 35 patients considered lack of communication with their doctors was an important factor. And through our record, we found mean for communication frequency was 2.54(SD, 0.89) for patients with medium or low compliance and 4.46(SD, 1.35) for patients with high compliance. The frequency of responses from doctors was significantly higher in patients with high compliance ($P < 0.001$). 20 patients also considered the worry about accuracy of their action as another important reason for giving up the system.

Primary Outcomes
ODI and VAS for EH and UC were similar at baseline and 3 months postoperatively. At 6 and 12 months, mean for change of ODI from baseline was -7.27 (SD, 5.31) for EH and -7.90 (SD, 4.53) for UC (Table 2). No significant difference was found between EH and UC at 6 months (P = .16) and 12 months (P = .87). But at 24 months, improvement in ODI was more significant in EH, compared with UC (P = .03). For VAS, the change was also not significantly different between EH and UC at 6 months (P = .27) and 12 months (P = .66). And at 24 months, mean for change of VAS from baseline was -22.36 (SD, 6.90) in EH and -29.95 (SD, 25.60) in UC. The improvement of VAS was more significant in EH than UC (P = .03) (Table 2).

Secondary Outcomes

No difference in Likert scale for movement was found at 3, 6 and 12 months postoperatively in EH and UC. At 24 months, patients in EH got superior results of Likert scale (mean of change: EH -32.51 [SD, 25.94], UC -22.54 [SD, 5.81], P = .01). (Table 2)

As for EQ5D, the change was similar for EH and UC at 3 months. At 6 months, the improvement for EQ5D was 0.23 (SD, 0.03) for EH and 0.13 (SD, 0.08) for UC. The patients in EH got a significantly superior result over that in UC. And this advantage sustained at subsequent time points (P < 0.001). (Table 2)

For SF 36, the improvement was more significant in EH compared with UC at 3, 6 and 24 months. (Table 2)

Subgroup analysis

In the EH group, 22 patients completed all the follow-ups, with average e-health attendance over 5 times per week, considered as high compliance. Thus, we conducted a subgroup analysis between these 22 patients with UC group.

Both the clinical and demographic characteristics were consistent between the two groups at baseline. There were no significant differences in the changes of ODI and VAS at 3 months. However, immediately posttreatment (6 months post-baseline), high compliance group was superior to UC group in posttreatment ODI (P = .003) and VAS (P = .01). And this advantage sustained at 12 and 24 months (Table 4).
Adverse Events

Adverse events, mostly mild self-limited joint and back pain, were reported in 9 EH and 6 UC participants. It did not differ significantly in frequency or severity of adverse events in these two groups.

Discussion

In this randomized controlled trial, we compared postoperative patients with lower back pain treated by E-health, a smart phone based tele-rehabilitation system (EH group), with those only received their surgeons’ usual practice (UC group). We found that EH group was superior to UC group at 24 months postoperatively. And no significant difference was found at all the other time points during following up. Further subgroup analysis showed that the improvements of the main outcomes were more significant in those considered as high compliance throughout the trial, in the EH group compared with the UC group at 6, 12 and 24 months. These results suggest that the prognosis of patients with high compliance to our tele-rehabilitation system tend to improve more significantly.

We aimed to explore the application of smartphone based rehabilitation in postoperative patients with lower back pain through a well-designed clinical trial. There are a lot of research been done to explore the effect of rehabilitation on the postoperative patients [9, 24-26]. Compared with previous experiments, all the patients in our study lived far away from the hospital and were unable to accept the traditional clinic based rehabilitation. This design was aimed to detect the effect of tele-rehabilitation, which is critically important in developing countries, where clinic based postoperative rehabilitation cannot be implemented, due to the extremely uneven distribution of health resources [27].

Thus, we developed a tele-rehabilitation system based on smartphone. Our system can guide patients through pictures, texts and videos. Meanwhile, this system makes it possible that doctors adjust the rehabilitation program in real time according to the progress of the patients' status. Also, it can provide a convenient way for patients to communicate with their doctors. All these designs were intended to improve the patient's compliance to rehabilitation protocol. But we found that our system only improved compliance of a part of patients. Through our records, we found that compared with patients with low compliance, the frequency of responses from doctors was significantly higher in patients with high compliance. Former studies also claimed communication
with doctors was vital for patients’ compliance. And digital technology should be applied to supplement interaction with patients [28, 29]. Besides the interaction with doctors, a survey of patients with medium and low compliance showed that the worry about the accuracy of their action was another important reason for giving up the system.

The above problems could be improved by optimizing designs in our system. Former studies have revealed that the smart phone is an effective tool in improving health behaviors of patients [30-32]. In Liu and colleagues’ study, patients with COPD were encouraged to perform daily endurance walking following the tempo of music from a program installed on a cell phone [33]. Dag, et al found that most of the adolescents with type I diabetes considered the mobile picture diary to be superior to paper-based systems [34]. Meanwhile, the smartphone can provide a lot of self-detecting methods: GPS positioning and gravity sensing technology to track elderly patients and provide timely feedback to medical staff [35]. the electrocardiogram, the blood glucose meter and the blood pressure meter connected through bluetooth can automatically upload the health-related data [36-38]. With the progress of technology, motion capture devices may also be applied in tele-rehabilitation. Till then, remote monitoring the accuracy of patients’ rehabilitation can be possible.

The limitation of our study is the relatively high lost follow-up rate. Due to the particularity of this study, patients included in our study had to travel long distance back to hospitals, adding the difficulty for following up. Electronic surveys have great potential to improve data collection [39]. A major advantage for applying electronic surveys is that they could increase the amount of data collected at a low cost [40]. Many researchers have explored the application of electronic versions of questionnaires. Terri et al found electronic versions of the Faces Pain Scale-Revised (FPS-R) and the Color Analog Scale (CAS) on a smartphone demonstrated good agreement with the original paper and plastic versions of these scales. [41]. Pawar et al found Software version of Roland Morris Disability questionnaire was comparable to the paper version in patients with low back pain[42]. While, other researchers found web or mobile device-based systems could facilitate consecutive patient data collection in RCTs and can be used to increase response rates and quality of research[43, 44]. Future studies should consider applying electronic tools to simplify the follow-up process and reduce loss to follow-up.

In conclusion, we found that E-health, a smart phone based tele-rehabilitation system was superior to usual care at 24 moths postoperatively in patients who were unable to accept the traditional clinic based rehabilitation. The effectiveness of E-health was more evident in high
adherent patients. E-health may be an effective rehabilitation tool for postoperative patient with low back pain, especially for those who have no access to traditional clinic-based rehabilitation. Smartphones are promising in the field of tele-rehabilitation. Still more studies are needed to found an optimal way to improve patients’ compliance.

Competing interests
The authors declare that no competing interesting exists. This study was financially supported by the Guangdong Medical Research Fund Project (C2015048) and Guangdong Natural Science Foundation (2015A030310321).


Table 1. Demographics and Baseline Characteristics of All Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>UC (n=84)</th>
<th>EH (n=84)</th>
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</thead>
<tbody>
<tr>
<td>Female gender, n (%)</td>
<td>42(50.00)</td>
<td>48(57.14)</td>
</tr>
<tr>
<td>Mean age (SD), y</td>
<td>49.36(9.52)</td>
<td>51.11(9.54)</td>
</tr>
<tr>
<td>Education status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school or lower n (%)</td>
<td>63(75.00)</td>
<td>60(71.43)</td>
</tr>
<tr>
<td>college degree or higher n (%)</td>
<td>21(25.00)</td>
<td>24(28.57)</td>
</tr>
<tr>
<td>Currently employed</td>
<td>62(73.81)</td>
<td>58(69.05)</td>
</tr>
<tr>
<td>Marriage status</td>
<td></td>
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</tr>
<tr>
<td>Married n (%)</td>
<td>76(90.48)</td>
<td>73(86.91)</td>
</tr>
<tr>
<td>Divorced n (%)</td>
<td>5(5.95)</td>
<td>6(7.14)</td>
</tr>
<tr>
<td>Single n (%)</td>
<td>3(3.57)</td>
<td>5(5.95)</td>
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Intervertebral discs involved in surgery

<table>
<thead>
<tr>
<th>Discs Involved</th>
<th>UC</th>
<th>EH</th>
</tr>
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<tbody>
<tr>
<td>1 disc n (%)</td>
<td>37(44.05)</td>
<td>36 (42.86)</td>
</tr>
<tr>
<td>2 discs n (%)</td>
<td>41(48.81)</td>
<td>41 (48.81)</td>
</tr>
<tr>
<td>3 discs n (%)</td>
<td>6(7.14)</td>
<td>7 (8.33)</td>
</tr>
</tbody>
</table>

Mean ODI score (SD)<sup>a</sup> 55.40(14.78)  54.14(15.18)
Mean VAS score (SD)<sup>b</sup> 60.11(15.99)  57.71(14.91)
Mean Likert score (SD)<sup>c</sup> 59.14(14.86)  59.71(16.49)
Mean EQ5D score (SD)<sup>d</sup> 35.75(15.37)  34.26(14.84)
Mean SF36 GH score (SD)<sup>e</sup> 13.55(5.58)  13.60(6.02)
Mean SF36 PF score (SD)<sup>e</sup> 21.11(8.36)  21.52(8.72)

Table 2 Primary Outcomes Change From Baseline and Between-Group Difference Outcomes

<table>
<thead>
<tr>
<th>Follow-up, mo.</th>
<th>Change from Baseline, Mean (SD)</th>
<th>Difference UC vs EH, Mean (SD)</th>
<th>P Value for Difference Between Groups</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>UC No.</td>
<td>EH No.</td>
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</table>

**a:** Rated to assess the patient’s level of disability due to lower back pain. Ranged from 0 to 100, with higher scores indicating more disability.

**b:** Rated between 0 and 100 with 100 representing worst pain possible.

**c:** Measured using an 11-point numerical rating scale for average difficulty for movement in the previous week, where 0 indicated no difficulty and 10 indicated most difficulty possible.

**d:** Rated between 0 and 100 with 100 representing a perfect health-related quality-of-life.

**e:** Ranging from 0 to 100, with higher scores indicating better health-related quality of life.
<table>
<thead>
<tr>
<th>Follow-up, mo.</th>
<th>No.</th>
<th>UC</th>
<th>No.</th>
<th>EH</th>
<th>Change from Baseline, Mean (SD)</th>
<th>Difference UC vs EH, Mean (SD)</th>
<th>P Value for Difference Between Groups</th>
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<tbody>
<tr>
<td>Likert score</td>
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<tr>
<td>3</td>
<td>80</td>
<td>-7.79 (4.96)</td>
<td>82</td>
<td>-7.20 (4.74)</td>
<td>0.20 (0.78)</td>
<td>.80</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>74</td>
<td>-13.51 (5.39)</td>
<td>77</td>
<td>-19.66 (26.47)</td>
<td>6.15 (3.08)</td>
<td>.05</td>
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<tr>
<td>12</td>
<td>70</td>
<td>-21.09 (5.68)</td>
<td>72</td>
<td>-23.00 (27.12)</td>
<td>1.91 (3.31)</td>
<td>.56</td>
<td></td>
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<tr>
<td>24</td>
<td>61</td>
<td>-22.54 (5.81)</td>
<td>60</td>
<td>-32.51 (25.94)</td>
<td>9.98 (3.43)</td>
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<td>EQ5D</td>
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<td>3</td>
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<td>0.09 (0.02)</td>
<td>82</td>
<td>0.09 (0.02)</td>
<td>0.00 (0.00)</td>
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<tr>
<td>6</td>
<td>74</td>
<td>0.13 (0.08)</td>
<td>77</td>
<td>0.23 (0.03)</td>
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<tr>
<td>12</td>
<td>70</td>
<td>0.17 (0.03)</td>
<td>72</td>
<td>0.24 (0.04)</td>
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<td>24</td>
<td>61</td>
<td>0.22 (0.04)</td>
<td>60</td>
<td>0.35 (0.03)</td>
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<tr>
<td>SF36 GH</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>80</td>
<td>38.16(2.43)</td>
<td>82</td>
<td>40.01(3.37)</td>
<td>-1.85 (0.46)</td>
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<tr>
<td>6</td>
<td>74</td>
<td>45.85(3.43)</td>
<td>77</td>
<td>54.75(4.59)</td>
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<tr>
<td>Follow-up, mo.</td>
<td>No.</td>
<td>UC</td>
<td>ODI</td>
<td>Change from Baseline, Mean (SD)</td>
<td>Difference UC vs EH, Mean (SD)</td>
<td>P Value for Difference Between Groups</td>
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<tr>
<td>12</td>
<td>70</td>
<td>55.53(3.86)</td>
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<td>56.25(5.31)</td>
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<td>24</td>
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<td>57.98(5.26)</td>
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<td>62.80(6.61)</td>
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SF 36 PF

<table>
<thead>
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<th>UC</th>
<th>VAS</th>
<th>Change from Baseline, Mean (SD)</th>
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<td>3</td>
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<td>30.58(2.29)</td>
<td>82</td>
<td>40.76(3.05)</td>
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<tr>
<td>6</td>
<td>74</td>
<td>46.35(3.62)</td>
<td>77</td>
<td>56.12(4.48)</td>
<td>-9.77 (0.66)</td>
<td>.00</td>
</tr>
<tr>
<td>12</td>
<td>70</td>
<td>56.13(4.79)</td>
<td>72</td>
<td>56.74(5.83)</td>
<td>-0.61 (0.89)</td>
<td>.49</td>
</tr>
<tr>
<td>24</td>
<td>61</td>
<td>59.07(5.89)</td>
<td>60</td>
<td>62.45(5.78)</td>
<td>-3.38 (1.06)</td>
<td>.02</td>
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Table 4: Subgroup Analysis of Primary Outcomes Change from Baseline and Between-Group Difference Outcomes

<table>
<thead>
<tr>
<th>Follow-up, mo.</th>
<th>No.</th>
<th>UC</th>
<th>VAS</th>
<th>Change from Baseline, Mean (SD)</th>
<th>Difference UC vs EH, Mean (SD)</th>
<th>P Value for Difference Between Groups</th>
</tr>
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<tbody>
<tr>
<td>3</td>
<td>80</td>
<td>-7.61 (5.15)</td>
<td>24</td>
<td>-6.42 (4.91)</td>
<td>-1.20 (1.19)</td>
<td>.32</td>
</tr>
<tr>
<td>6</td>
<td>74</td>
<td>-14.19 (5.11)</td>
<td>24</td>
<td>-33.75 (25.67)</td>
<td>19.56 (5.27)</td>
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