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## Enhancing Psychosocial Well-being: The Application of Acceptance and Commitment Therapy in Patients Following Amputation

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#### Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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#### **ABSTRACT**

**Objective:** This study aims to examine the impact of Acceptance and Commitment Therapy (ACT) on individuals post-amputation.

**Methods:** A total of 100 post-amputation patients admitted to the Department of Traumatic Hand and Foot Surgery at X Hospital between October 2022 and April 2023 were selected using a convenient sampling method. Through random assignment, participants were divided into a control group and an experimental group (50 participants each). The control group received standard nursing care, while the experimental group underwent Acceptance and Commitment Therapy. Preintervention and post-intervention assessments, at three and six months, included evaluations of

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psychological flexibility, stigma, and disability acceptance.

**Results:** Forty-eight participants in the control group and 47 in the experimental group completed the study. Following the intervention, the experimental group exhibited significantly lower scores on the Acceptance and Action Questionnaire (AAQ-II) and Social Impact Scale (SIS) compared to the control group (P < 0.05). Disability acceptance, measured by the Acceptance of Disability Scale-Revised (ADS-R), was higher in the intervention group, and the difference was statistically significant (P < 0.05). Acceptance and Commitment Therapy demonstrated efficacy in enhancing mental flexibility, fostering disability acceptance, and reducing stigma post-amputation.

**Conclusion:** Acceptance and Commitment Therapy proved effective in enhancing psychological flexibility, promoting disability acceptance, reducing stigma, and facilitating reintegration into society among post-amputation patients.

Keywords: Amputation; surgical; China; disabled persons; therapeutics.

#### 1. INTRODUCTION

Currently, the number of people with physical disabilities in China is approximately 85 million, accounting for 6.21% of the total population, and this trend is increasing yearly [1]. Amputation surgery results in permanent loss of limb function, changes in self-image, profound impact on psychological flexibility, and different degrees of stigma [2]. Studies have shown that disability acceptance is closely related to stigma, which can affect the mental health of patients [3]. However, there are few studies on the mental flexibility of patients after amputation in China, and intervention methods lack reliability and validity.

Therefore, the development of valid intervention measures for the mental flexibility of patients after amputation is urgently needed. Acceptance and Commitment Therapy (ACT) is one of the psychotherapy methods for generation cognitive and behavioral therapy. It was founded by Steven C. Hayes, a Doctor of American psychology, in the 1980s [4]. Therapy is philosophically based in a functional context, incorporating Eastern philosophy and aiming to improve mental flexibility through commitment, self-acceptance, and actions based on self-worth. This therapy has been widely used to treat various psychological diseases and malignant tumors [5]. Based on study applied acceptance commitment therapy to rehabilitate patients after amputation to enhance the patient's psychosocial well-being.

#### 2. METHODS

#### 2.1 Research Design

This study select the retrospective design research.

#### 2.1.1 Setting and sampe

From October 2022 to April 2023, the research subjects used the a randomized control trial method to select patients hospitalized after amputation in the Department of Trauma Hand-Foot Surgery of X Hospital. This random allocation method can eliminate the influence of selection bias and grouping bias, and thus draw accurate conclusions. Based on the sample size estimation formula:  $N=4[(U2/\alpha+U\beta)2\sigma2]/\delta2$ , where  $\alpha$ =0.05,  $\beta$ =0.10,  $\delta$ difference in scores between two clinically significant groups,  $\delta$  The larger of the estimated values representing the standard deviation of the two groups of populations, based on the pre-experimental results and considering a 10% loss of follow-up rate, was obtained as a sample size of 100 cases per group, and were randomly divided into a control group (50 patients) and an experimental group (50 patients).

The inclusion criteria were as follows: (1) Patients with amputation; (2) age ranging from 18 to 65 years; (3) stable condition and ability to communicate normally; and (4) informed consent and voluntary participation in this study. The exclusion criteria were as follows: (1) patients receiving other psychological treatments, and (2) patients with severe cardiovascular and cerebrovascular complications.

### 2.1.2 Intervention methods of the intervention group

The following interventions were performed: (1) Program formulation: An intervention team for acceptance and commitment therapy was established, with the hexagonal psychotherapy model of acceptance and commitment therapy as the theoretical framework [6], and referred to Liu June [7]. The research team developed an intervention outline for acceptance and

commitment therapy, and designed an initial intervention plan. Finally, the expert focus meeting method obtained the final intervention plan; (2) intervention time—the baseline data survey was completed before surgery, and acceptance and commitment therapy intervention began on the second day after surgery for four weeks, with each intervention lasting about 60-90 minutes; and (3) the intervention plan was as follows:

#### 2.1.2.1 Intervention plan

#### 2.1.2.1.1 Acceptance (1week)

**Intervention goals:** To promote mutual understanding between the intervener and the patient and familiarize themselves with the intervention content, to help patients understand the knowledge of rehabilitation after amputation, and to promote their acceptance of the stump.

#### Interventions:

- a. First, introduce yourself and the patient to ACT therapy to establish a therapeutic relationship (approximately 10 min). The intervention objectives were clearly defined and informed consent was obtained.
- Discuss current concerns and thoughts with the patient. Guide patients to selfacceptance and help them face their current life status with a positive attitude.
- c. Mindfulness practice. Systematic understanding of postoperative precautions (approximately 30 min). By playing relevant videos and introducing them by researchers or nurses, patients can systematically master the knowledge related to the postoperative rehabilitation of amputation, postoperative stump care, phantom limb pain, maintenance of functional position, and other contents to promote the acceptance of the stump.
- d. Week 1: Effect feedback (approximately 10 minutes). Patients shared the harvest in the first week, and the intervener encouraged the patient to provide comments and suggestions for the first week.
- 2.1.2.1.2 Cognitive dissociation, experience the present moment (2 week)

**Intervention goals:** Through the patient's description of the pain caused by the stump and the coping effect, the intervener introduced the

method of "cognitive dissociation" to enable the patient to learn cognitive dissociation and reduce the psychological pain caused by the stump.

#### Interventions:

- a. Patients expressed the effects of surgery on limb function and psychological society and were encouraged to share their feelings, coping styles, and effects (about 30 minutes). Help patients realize that "life is full of ups and downs," accept the fact of the stump, and face the changes brought by the stump after surgery with a positive attitude.
- b. Introduction to "Cognitive Dissociation" method. Through the principle of ACT treatment, patients can be helped to accept the fact that they have lost their limbs, take active remedies, wear prosthetic limbs to recover certain self-care abilities, and get out of negative emotions as soon as possible. min (approximately 30 min), respectively.
- c. Week 2: Effect feedback. Patients shared the harvest in the second week; they were encouraged to make comments and suggestions at week 2 (about 10 minutes).
- 2.1.2.1.3 Focus on yourself and learn about mindful breathing and mindfulness meditation (3 week)

**Intervention goals:** Promote awareness of the present and situational self and learn mindful breathing and meditation.

#### Interventions:

- a. The researchers instructed the patients to learn about mindful breathing and mindfulness meditation and encouraged them to practice daily to improve their ability to be aware of the present moment (about 30 minutes).
- b. Take oneself as a scene. Members share measures to improve limb function with each other face-to-face or through WeChat groups, actively cooperate with treatment and rehabilitation exercises, and change painful emotions, such as impaired dignity and fear (about 40 minutes).
- Homework: Practice mindful breathing and mindfulness meditation, and experience yourself in different situations.
- d. Week 3: Effect feedback. Patients shared the harvest in the third week: the

intervener encouraged the patient to put forward the comments and suggestions of the third week (approximately 10 minutes).

### 2.1.2.1.4 Clarify values and commit to action (4 week)

**Intervention goals:** Guide patients to apply acceptance actions to real life, deal with bad emotions in life through mindfulness, and change their current life through commitment to action.

#### Interventions:

- a. Through the first few interventions, patients shared changes, such as emotional pain, sense of worth, and sense of dignity, to further clarify their self-worth and establish confidence in accepting and coping with disability. (about 30 min)
- b. Commit to action. Each patient who underwent surgery for limb function change, lifestyle changes, and the impact of psychosocial function put forward feasible measures and promised action; researchers encouraged patients to live in the present moment, maintain normal, reduce emotional distress, and at the same time, follow their own interests and hobbies, and meaningful valuable life. min (approximately 40 min), respectively.
- c. Homework: Encourage patients to keep a diary of their disability coping.
- d. Week 4: Effect feedback ① Patients shared the harvest in week 4; ② The intervener encouraged the patient to put forward the comments and suggestions of the fourth week (about 10 minutes).

#### 2.1.3 Control group intervention method

The control group underwent routine nursina measures, which mainly included post-operative stump nursing, phantom limb pain, maintenance of functional position, prosthesis, complication guidance. Discharge education, regular telephone follow-up, and regular reexamination in the hospital. ΑII patients the control and experimental groups completed the baseline data survey before surgery and were followed-up at 3 and 6 months after surgery.

#### 2.1.4 Evaluation method

(1) The Acceptance and Action Questionnaire-2nd Edition (AAQ-II) was developed by

- Bond et al. [8]. Preparation measures the degree of empirical avoidance. The questionnaire consists of seven items rated as 1-7 points, with one indicating never and 7 indicating often. The total score for the seven items was 7-49 points. The higher the score, the higher the degree of experiential avoidance and the lower the psychological flexibility is lower (Jing Tseng et al.) [9]. The Cronbach 'sa coefficient of the questionnaire is 0.88, which has good reliability and validity and can be used in the Study of Empirical Avoidance and Commitment Therapy.
- (2) The Chinese version of the Social Impact Scale (SIS) was compiled by File et al. [10], Pan et al [11], and Sinicization was carried out. The 24 items included four dimensions: economic discrimination, social exclusion, social isolation, and internal shame. The former are internal stigma discrimination, whereas the latter are real stigma and discrimination. The total score for the four dimensions was 24-96 points. The higher the score, the stronger is the perceived shame. The Cronbach's a coefficients of the scale ranged from 0.85 to 0.90, with good reliability and validity.
- (3) The Acceptance of Disability Scale-Revised (ADS-R) was developed by Groomes et al. [12] and Chen Ni et al. [13]. It is often used to investigate acceptance of disability in patients with limb injuries. There were 32 items in total, including four dimensions: expansion, inclusion. subordinate, and transformation. From "strongly disagree" to "strongly agree," the score is 1-4, and the total score is 32-128. The higher the score, the higher the patient's disability acceptance level. The Cronbach's α coefficient of this scale was 0.83, indicating good reliability and validity.

#### 2.2 Data Collection

From October 2022 to April 2023, the intervention results were evaluated by conducting a questionnaire survey before and after the intervention in the control and experimental groups at the Department of Trauma Hand-Foot Surgery of X Hospital. Finally, 95 patients completed the study: control group (48 patients) and experimental group (47 patients). The 2 losse patients of control group were ruled out due to the occurrence of new complications. The reason why 3 patients in the experimental group were excluded was that they

automatically discharged from the hospital and were unable to contact the patients.

#### 2.3 Statistical Methods

SPSS software (version 23.0) was used for the statistical analysis. statistical method using  $\chi 2$  test to comparison of basic information between the two groups of patients. An Independent sample t-test was used to compare baseline AAQ-II, SIS, and ADS-R scores between the experimental and control groups. Repeated measures ANOVA was used to compare the effects at different time points between the two groups after the intervention.  $P \le 0.05$  was considered statistically.

#### 3. RESULTS

During research, The 2 losse patients of control group were ruled out due to the occurrence of new complications and The 3 losse patients of experimental group were ruled out due to the occurrence of new complications. Finally, 95 patients completed the study: control group (48 patients) and experimental group (47 patients).

## 3.1 Comparison of the Demographic Data between the Two Groups of Patients

In this study, the  $\chi 2$  test was used to compare basic information between the two groups of patients. The differences were not statistically significant in age, sex, professional post, marital status, education level, time after amputation(days), amputation reasons, amputation level, and perceived pain level between the two groups (P > 0.05). Further details are provided Table 1 for details.

## 3.2 Comparison of the Baseline of All Scales's Scores

Baseline comparison of the scores of all scales between the experimental and control groups showed no statistical significance in the scores of all evaluation indexes between the two groups (P > 0.05). Further details are provided Table 2 for details.

#### 3.3 Comparison of the AAQ-II Scores

The comparison of AAQ-II scores between the two groups before and after intervention indicated that there was a statistically significant difference in the time effect of the AAQ-II score between the experimental group and control

group (P < 0.01), and the psychological flexibility of patients gradually improved with the extension of postoperative time (Table 3).

#### 3.4 Comparison of the Stigma Scores

The comparison of stigma scores between the two groups before and after intervention showed that there was a statistically significant difference in the time effect of SIS scale scores between the experimental group and control group (P < 0.05), and the patients' stigma gradually decreased with the extension of post-operative time (Table 4).

## 3.5 Comparison of Disability Acceptance Scores

The comparison of disability acceptance scores between the two groups before After the intervention, the time effect of the ADS-R score of the test group and control group was statistically significant (P < 0.05), and the disability acceptance of patients increased gradually with the extension of post-operative time, as shown in Table 5.

#### 4. DISCUSSION

# 4.1 Acceptance and Commitment Therapy can Improve the Psychological Flexibility of Patients after Amputation

Mental flexibility is the ability of individuals to focus their attention on the current realistic environment and take meaningful actions based on the correct values to achieve their aspirations. Mental flexibility is at the core of acceptance and therapy [14]. This study showed that the AAQ-II score of the experimental group was significantly lower than that of the control group after the intervention (P < 0.01). This suggests that the nursing intervention flexibility of patients after amputation is consistent with Han et al. [15]. According to acceptance and commitment therapy can improve psychology, and the results were consistent. After amputation, patients not only have to face the inconvenience of life and work brought about by limb deformity, but also face other people's strange eyes. In the long run, it can lead to reduced social activities and personality changes, resulting in avoidance behavior. In addition, post-operative stump pain, phantom limb pain, stump deformity contracture, and other complications tend to cause anxiety, depression, irritability, and other adverse

emotions, resulting in a general decrease in commitment therapy improves patients' mental psychological flexibility. Acceptance and flexibility.

Table 1. Comparison of general information between the two groups of patients

| Project                 | Experimental group (n=47) | Control group (n=48) | Test statistic      | P-value |
|-------------------------|---------------------------|----------------------|---------------------|---------|
| Gender                  | <b>,</b>                  | , ,                  | 0.2681)             | 4.851   |
| Men                     | 27(57.4)                  | 27(56.3)             |                     |         |
| Women                   | 20(42.6)                  | 21(43.7)             |                     |         |
| Age(years)              |                           |                      | 0.121 <sup>1)</sup> | 7.415   |
| ≥18                     | 7(15.0)                   | 8(16.8)              |                     |         |
| 19~<40                  | 20(42.5)                  | 20(41.6)             |                     |         |
| 40~<65                  | 20(42.5)                  | 20(41.6)             |                     |         |
| Professional post       |                           | , ,                  | 0.113 <sup>1)</sup> | 7.532   |
| Famer                   | 7(14.8)                   | 7(14.5)              |                     |         |
| Merchant                | 8(17.0)                   | 9(18.7)              |                     |         |
| Teacher                 | 10(21.2)                  | 10(20.8)             |                     |         |
| Accounting              | 5(10.6)                   | 5(10.4)              |                     |         |
| Nurse                   | 2(4.2)                    | 2(4.1)               |                     |         |
| Worker                  | 9(19.1)                   | 9(18.7)              |                     |         |
| Freelance               | 6(13.1)                   | 6(12.8)              |                     |         |
| Marital status          | • •                       | , ,                  | 0.0341)             | 9.561   |
| Married                 | 19(40.4)                  | 12(25.0)             |                     |         |
| Divorced                | 17(36.0)                  | 19(39.5)             |                     |         |
| Single                  | 21(44.6)                  | 27(35.5)             |                     |         |
| Educational level       | ,                         | , ,                  | 1.621 <sup>1)</sup> | 3.191   |
| Diploma                 | 17(36.1)                  | 18(37.5)             |                     |         |
| Associate degree        | 1Ò(21.2)                  | 10(20.8)             |                     |         |
| Bachelor's degree       | 20(42.7)                  | 20(41.7)             |                     |         |
| Time after              |                           | , ,                  | 0.020 <sup>1)</sup> | 9.891   |
| amputation (days)       |                           |                      |                     |         |
| 31-<180                 | 17(36.1)                  | 18(37.5)             |                     |         |
| 181-<365                | 9(19.1)                   | 10(20.8)             |                     |         |
| ≥365                    | 21(44.8)                  | 20(41.7)             |                     |         |
| Amputation reasons      | = 1(1110)                 |                      | 0.031 <sup>1)</sup> | 7.121   |
| Trauma                  | 16(34.0)                  | 17(35.4)             |                     |         |
| Vascular disease        | 10(21.2)                  | 11(22.9)             |                     |         |
| Diabetes                | 21(44.8)                  | 21(41.7)             |                     |         |
| Amputation level        | ( -7                      | \ /                  | 0.0671)             | 10.113  |
| Proximal thigh (left    | 6(12.7)                   | 3(6.2)               |                     |         |
| side)                   | - ( )                     | - ( - )              |                     |         |
| Proximal calf (left     | 9(19.1)                   | 7(14.5)              |                     |         |
| side)                   | · - /                     | · -/                 |                     |         |
| Foot (left side)        | 7(14.8)                   | 6(12.5)              |                     |         |
| Distal thigh (right     | 5(10.6)                   | 5(10.4)              |                     |         |
| side)                   | - ( /                     | -(/                  |                     |         |
| Distal leg (right side) | 5(10.6)                   | 5(10.4)              |                     |         |
| Foot (right side)       | 6(12.7)                   | 7(14.5)              |                     |         |
| Proximal thigh          | 7(14.8)                   | 9(18.7)              |                     |         |
| (bilateral)             | . (1.1.0)                 | 0(10.1)              |                     |         |
| Proximal calf (right    | 2(4.7)                    | 6(12.8)              |                     |         |
| , -                     | 2(4.1)                    | 0(12.0)              |                     |         |
| side)                   |                           |                      | 0.0211)             | 0.904   |
| Perceived pain level    | 27/57 4)                  | 20/50.2\             | 0.0211)             | 9.891   |
| Severe                  | 27(57.4)                  | 28(58.3)             |                     |         |
| Moderate                | 10(21.3)                  | 9(18.7)              |                     |         |
| Mild                    | 10(21.3)                  | 11(23.0)             |                     |         |

Note: 1) χ²-value

Table 2. The baseline scores of each scale were compared between the experimental group and the control group (X±s)

| Total score of each scale | Experimental group (n=47) | Control group<br>(n=48) | t     | P     |  |
|---------------------------|---------------------------|-------------------------|-------|-------|--|
| AAQ-II                    | 39.12±9.146               | 37.78±7.377             | 1.567 | 0.218 |  |
| SIS                       | 53.30±10.328              | 55.08±8.380             | 0.818 | 0.338 |  |
| ADS-R                     | 51.120±7.380              | 50.120±7.310            | 1.871 | 0.518 |  |

Note: t = two-group t-test; AAQ-II: Acceptance and Action Questionnaire; SIS: The stigma score; ADS-R: Disability Acceptance score

Table 3. Repeated measures ANOVA of psychological flexibility (AAQ-II) between two groups

| Group         | n  | Base line | 3 months | 6 months | <b>F</b> time | <b>P</b> time | <b>F</b> group | <b>P</b> group |
|---------------|----|-----------|----------|----------|---------------|---------------|----------------|----------------|
| Experimental  | 47 | 39.12±    | 26.33±   | 20.26±   | 11.143        | < 0.01        | 6.234          | < 0.05         |
| group         |    | 9.146     | 5.680    | 7.621    | _             |               |                |                |
| Control group | 48 | 37.78±    | 28.06±   | 24.22±   |               |               |                |                |
|               |    | 7.377     | 7.232    | 6.777    |               |               |                |                |
| t             |    | 1.567     | -0.917   | -3.149   |               |               |                |                |
| P             |    | >0.05     | < 0.05   | < 0.01   |               |               |                |                |

Note.t=two group t-test;F=repeated measures ANOVA

Table 4. SIS repeated measures ANOVA between two groups (X±s)

| Group         | n  | Base line | 3 months | 6 months | <b>F</b> time | <b>P</b> time | <b>F</b> group | <b>P</b> group |
|---------------|----|-----------|----------|----------|---------------|---------------|----------------|----------------|
| Experimental  | 47 | 53.30±    | 43.88±   | 38.96±   | 8.817         | < 0.01        | 6.212          | <0.05          |
| group         |    | 10.328    | 8.715    | 11.292   | _             |               |                |                |
| Control group | 48 | 55.08±    | 51.72±   | 49.88±   |               |               |                |                |
|               |    | 8.380     | 10.390   | 8.655    |               |               |                |                |
| t             | •  | 0.818     | -2.002   | -3.241   |               | •             | •              |                |
| Р             |    | >0.05     | <0.05    | < 0.05   |               |               |                |                |

Note.t=two group t-test;F=repeated measures ANOVA

Table 5. ADS-R repeated measures ANOVA of two groups (X±s)

| Group         | n  | Base line | 3 months | 6 months | <b>F</b> <sub>time</sub> | P <sub>time</sub> | <b>F</b> group | Pgroup |
|---------------|----|-----------|----------|----------|--------------------------|-------------------|----------------|--------|
| Experimental  | 47 | 51.120±   | 59.18±   | 68.96±   | 9.117                    | < 0.01            | 5.132          | < 0.05 |
| group         |    | 7.380     | 8.115    | 11.292   |                          |                   |                |        |
| Control group | 48 | 50.120±   | 54.32±   | 59.88±   |                          |                   |                |        |
|               |    | 7.310     | 10.370   | 10.655   |                          |                   |                |        |
| t             |    | 1.871     | -2.102   | -2.241   |                          |                   |                |        |
| Р             |    | >0.05     | <0.05    | < 0.05   |                          |                   |                |        |

Note.t=two group t-test; F=repeated measures ANOVA

## 4.2 Acceptance and Commitment Therapy can Reduce the Stigma of Patients after Amputation

Stigma is a negative emotional experience in which patients feel shame and self-stigmatization due to image changes and social discrimination caused by the disease [16]. The study indicated that The SIS score of the experimental group was lower than that of the control group after the

intervention (P < 0.05). Nursing interventions based on acceptance and commitment therapy can reduce the stigma of patients after amputation, similar to the findings of Bettlach et al. [17]. These results were consistent. The reasons for this are as follows: acceptance and commitment therapy guides patients to accept objective facts, helps them adjust their mentality, cognitively dissociates themselves, and objectively interprets current events.

Moreover. mindfulness meditation eliminates patients' shame, avoidance, and other unspeakable painful experiences and reduces their sense of shame. At the same time, by clarifying their value, patients are guided to summarize their own experience in stump rehabilitation training and absorb indirect experiences of patients, to promote the recovery of stump function as soon as possible, and to encourage patients to make contributions to society by relying on their ability and making their value to the family and society. Finally, they commit to action to change the current life situation.

## 4.3 Acceptance and Commitment Therapy can Improve Disability Acceptance of Patients after Amputation

The degree of disability acceptance refers to the degree to which an individual accepts his or her disability status and how the disabled individual responds to physical changes and the impact on existing life through values and adaptability to social life [18]. The Study indicated that the ADS-R scale score of the experimental group was significantly higher than that of the control group after the intervention (P < 0.05). It has been suggested that nursing interventions based on acceptance and commitment therapy improve disability acceptance in patients after amputation [17]. The research results were consistent. With the development of social psychology, disability acceptance has become a new research perspective and a hot research topic for scholars worldwide. Studies have shown that [19], Because of the physical disability caused by trauma and disease, patients negate their value and social value, often devaluing their health and ability. Through acceptance and cognitive dissociation, the patient can perceive the evaluation of the outside world and himself as an observer and help the patient adjust the relationship between himself and the evaluation rather than closely associating himself or herself with the evaluation. Cognitive dissociation technology enables patients to understand that these evaluations are just external opinions and do not represent themselves. It guides them to keep a distance from themselves, so that they can see themselves more truly and reduce their experience of stigma.

#### 5. CONCLUSION

With the change in the modern medical model, from simple symptom management to the overall

health of the body and mind, nursing staff should master cutting-edge psychological intervention skills, actively pay attention to the psychological state of patients, and implement corresponding interventions for patients with different types of psychological disorders to achieve their overall health and spiritual growth. In acceptance and commitment therapy can improve patients' psychological flexibility and disability acceptance after amputation, reduce the stigma of patients, and promote the return to society; however, due to time constraints, this study only observed the experimental effect six months after the intervention, and the long-term effect of intervention remains to be further studied. Based on this, this study applied acceptance and commitment therapy rehabilitate patients after amputation and achieved good results, providing a new direction and target for psychological intervention in patients after amputation.

#### **CONSENT AND ETHICAL APPROVAL**

The present study was registered (no. ChiCTR2200066164) at the Chinese Clinical Trial Registry and its ethical document review (Approval no.20X2), the study was approved by the X Hospital and agreed upon by the relevant participants.

#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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