Effect of Post-Hospital Discharge Follow-up on Health Status in Patients with Burn Injuries: A Randomized Clinical Trial

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ABSTRACT

Background: Patients with burn injuries still face various burn-related challenges after being discharged from the hospital. Hence, a follow-up program for such patients is essential. The present study aimed to evaluate the health status of burn victims after 1.5 months follow-up.

Methods: The present randomized clinical trial was of a pretest-posttest design, carried out in Kermanshah (Iran) from July 2016 to September 2017. A total of 117 participants were recruited out of which 86 were included in the analysis. The participants were randomly assigned into two groups, namely the intervention group (N=42) and the control group (N=44). All participants were evaluated both at the time of hospital discharge and at 1.5 months post-discharge. The follow-up plan for the intervention group included home visits, telenursing, and referral to specialists or health education centers. To evaluate the physical and psychological status of the participants, five different instruments were used; namely the Burn Specific Health Scale-Brief (BSHS-B), the General Health Questionnaire-28 (GHQ-28), the Brief Pain Inventory (BPI), the Vancouver Scar Scale (VSS), and the Visual Analogue Scale (VAS). All statistical analyses were performed using the SPSS software (version 17.0). Data were analyzed using the Chi-square test, independent t-test, and paired t-test. P<0.05 was considered statistically significant.

Results: The mean score of the BSHS-B questionnaire at both the time of discharge and 1.5 months post-discharge follow-up for the control and intervention groups was 61.22±19.07, 57.14±18.92; 83.70±24.73 and 105.16±29.17, respectively. There was a significant difference between the groups at 1.5 months post-discharge follow-up (P<0.001). At 1.5 months, the VSS score was 5.16±1.68 and 6.77±3.46 for the intervention and control groups, respectively. The GHQ-28 score was 28.69±12.39 and 40.79±16.20 for the intervention and control groups, respectively. The VAS and BPI scores of the control group were 5.56±3.11 and 21.93±29.25, respectively. For the intervention group, these scores were 4.85±3.49 and 15.61±27.47, respectively. There was a significant difference between the groups as to the GHQ and VSS scores (P<0.05). However, no significant difference was noted in the BPI and VAS scores (P<0.05).

Conclusion: Health status, psychological status, and scar management were improved due to post-discharge follow-up. However, burn patients required continued care for pain, psychological health, and itching problems.

Trial Registration Number: IRCT2016110630712N

KEYWORDS: Aftercare, Burns, Follow-up care, Health status, Home visits

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INTRODUCTION

Burn trauma is a serious event for the affected person, their families, the community, and the nation as a whole. Burn injuries are destructive and associated with impairment of Quality of Life (QOL), emotional well-being, and morbidity. Serious burns will impose major restrictions on the victims and introduce barriers to a productive life. After hospital discharge, burn victims still suffer from physical and psychological problems (e.g. skin problems, pain, itching, distress, low self-esteem, anxiety, depression, and post-traumatic stress disorder). The effects of burn injuries lead to permanent disability, and thus the QOL of burn victims and their families is disrupted. Health-Related Quality of Life (HRQOL) encompasses physical, psychological, and social domains. Both the HRQOL and physical activity of such patients are reduced 36 months after a burn injury. For adult patients, a minimum of a one-year rehabilitation period along with physiotherapy and scar management is required.

The process of transferring a burn patient from hospital to home is a complex and intense event due to the fact that the primary care of patients give over to the patients and their families. As a result, at the time of hospital discharge, patients feel the anxiety of going home as they are insecure about the lack of amenities to meet their physical, psychological, and medical needs. At home, they face various problems and decisions, as well as financial and emotional challenges. Following hospital discharge, patients experience various burn-related consequences. Hence, the follow-up of burn patients and their families is crucial.

Follow-up care is an element of aftercare and can be performed through home visits and/or telenursing. Some of the advantages of aftercare are reduced rehospitalizations (and thus lower costs), which in turn enhances patients’ satisfaction level and encourages them to continue with complementary treatments. Without this extra care, burn victims will have less motivation for further treatments, which exacerbate issues related to post-hospital discharge. A follow-up by telephone increases the likelihood of patients to attend burn clinics for specialized interventions, the continuation of treatments, and interaction with health care providers and other patients to learn about the effect of various treatments.

In Iran, despite the benefits of aftercare, community health services are not as advanced as hospital services. A change in the Iranian healthcare system toward improving community health services would benefit the home health care system. Burn treatments require a long-term multidisciplinary care to manage the complex problems associated with severe burns. During the first year after suffering from burn injuries, patients may endure different psychological problems, alteration in health status, and body image. Therefore, a follow-up program is recommended for such patients.

The HRQOL, disease-related knowledge, and patients’ satisfaction can be improved through home health care. In addition, patients’ self-efficacy, physical activity, and adherence to treatment improved by telenursing in Iran. Although there are reports of increased hospital admissions and prevalence in Iran, there is no follow-up care for burn patients. Hence, the present study aimed to evaluate the effect of post-hospital discharge follow-up on the health status of burn patients.

MATERIALS AND METHODS

The present randomized clinical trial (RCT) was of a pretest-posttest design, carried out in Kermanshah (Iran) from July 2016 to September 2017. A total of 117 participants were recruited out of which 86 were eventually included in the analysis. The participants were randomly assigned into two groups, namely the intervention group (N=42) and the control group.
The intervention started from baseline (at discharge) to 1.5 months post-discharge. The inclusion criteria were age ≥18 years, burn severity >15% (second-degree or third-degree burns), awareness of time-place-person, ability to answer the questionnaires, no history of burn injuries or hospitalization, and no history of severe psychological disorders. The exclusion criteria were migration, not responding to follow-up phone calls, or withdrawal from the study.

The sample size (95% confidence level and 90% statistical power) was calculated using the below formula:

\[ n = \frac{2 \sigma^2 \left( \frac{Z_{1-\alpha} + Z_{1-\beta}}{\mu_1 - \mu_2} \right)^2}{(\mu_1 - \mu_2)^2} \]

The calculated sample size was 38 patients per group. Note that SD (11) and the mean difference (7) were calculated based on a study by Kvannli and colleagues. By considering a 20% attrition rate, the final sample size for both groups was 45. Eventually, 86 patients remained in the study and were included in the analysis. (Figure 1)

The convenience sampling method was used and patients fulfilling the inclusion criteria were recruited at the time of hospital discharge. Block randomization design was applied to ensure equal distribution of patients with different depth and severity in both the control and intervention groups. For random allocation, the PASS software was used to create a randomized list. There were two groups (including the control and intervention groups) with block size 8, list length 90, and two strata (category A: burn severity between 15%-25%, category B: burn severity >25%). The clinical staff at the burn center was blinded to the intervention.

The burn center in Kermanshah (Iran) is an educational hospital and has both a burn

![Figure 1: CONSORT 2010 flow diagram of the participants]
ward and a clinic. The study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran (ID: SBMU2. Rec.1394.168).

Initially, upon hospital discharge, all patients in the control and intervention groups were evaluated. Demographic information was collected and a written informed consent was obtained from the participants. The instruments used in the study are described below.

**Burn Specific Health Scale-Brief (BSHS-B)**

The BSHS-B was developed by Kildal and colleagues in 2001 to measure the general health, physical, mental, and social domains of burn patients. It includes 40 questions, 9 subscales, and 3 domains. The physical domain includes 4 sub-scales of simple abilities, hand function, heat sensitivity, and treatment regimen. The mental domain includes affect and body image. The social domain includes interpersonal relationship, sexuality, and work. The scoring is based on a 5-point Likert scale from 0 (none) to 4 (severe inability) with a maximum total score of 160. Higher scores represent a better health status. Reliability and validity of the BSHS-B were confirmed in a population of burn patients in a previous study in Iran. Construct validity was assessed by the known group technique and exploratory factor analysis. The reliability of BSHS-B was evaluated for internal consistency and test-retest reliability. Internal consistency of the total instrument was $\alpha=0.94$. Moreover, the test-retest reliability showed that the Intraclass Correlation Coefficient (ICC) ranged from 0.81 to 0.96 with a total score of 0.93.18, 21

**General Health Questionnaire-28 (GHQ-28)**

The GHQ-28 was developed by Goldberg in 1978 to detect probable psychiatric disorders.22 It includes four sub-scales of somatic symptoms, anxiety and insomnia, social function, and severe depression with a maximum total score of 84. Higher scores represent poor psychological health. The scoring is based on a 4-point Likert scale from 0 (never) to 3 (very much). The scores for all dimensions ranged from 0 to 21, with the cut-off point at 23 to determine psychological problems.23 Scores higher than 6 indicate an abnormality in each sub-scales.24 Concurrent validity and test-retest reliability ($r=0.85$) of the questionnaire were measured in a previous study in Iran.25 In the present study, reliability in terms of internal consistency was acceptable ($\alpha=0.81$).

**Brief Pain Inventory (BPI)**

The BPI was developed by Cleeland in 1991. It has 15 items, of which 11 items have numeric rating scale, on the experience of pain, the area of severe pain, the presence of pain, minimum and maximum pain on the previous day, current pain level, analgesia and pain relief, and the interference of pain on the patient’s functioning. For 11 items, the score ranged from 0 (no pain) to 10 (worst imaginable pain) with the maximum total score of 110. Higher scores indicate more severe pain.26 The Persian version of the BPI, after translation and validation study, was developed by Majedi and colleagues in 2017. Construct validity was assessed by factor analysis. The Comparative Fit Index (CFI) was 0.92. Reliability in terms of internal consistency was assessed ($\alpha=0.85$) and test-retest reliability was more than 0.80.27 In the present study, reliability in terms of internal consistency was acceptable ($\alpha=0.89$).

**The Vancouver Scar Scale (VSS)**

The VSS was developed by Sullivan and colleagues in 1990.28 It includes four parameters for scar assessment, namely pigmentation, pliability, height, and vascularity. The score range from 0 to 13 and higher scores indicate more scar severity.29, 30 Face and qualitative content validity of the instrument were assessed after translation of the scale. The inter-rater reliability of the instrument was evaluated by the first author and a clinical nurse. The scar of 10 patients was assessed and the reported inter-rater reliability was 0.81. Inter-rater reliability of
The Visual Analogue Scale (VAS)

The VAS was used for the first time by Hayes and Patterson in 1921 to determine the severity of itching in the burn area.32, 33 VAS is a 10-cm line where the beginning of the line indicates no itch (score 0) and the end represents worst itch (score 10).34 The content validity and ICC (0.88) were evaluated in a previous study.35 The VAS was confirmed as a valid, reliable, and repetitive method for the evaluation of itch.36

The participants in the control group received the routine care from the burn clinic. Those in the intervention group, in addition to the routine care, received follow-up care (home visits and telenursing) for 1.5 months which was sooner for serious cases. A few days after hospital discharge, sooner home visit based on patients’ need, the patients in the intervention group were contacted by phone to plan a schedule for the home visits. During the first home visit, variables such as signs of infection, changes in vital signs, nutrition, edema, medications, itching, and changes in Range of Motion (ROM) of the joints were evaluated. Upon wound healing, the focus of the assessment shifted to scar formation, scar contracture, limitation in ROM, and changes in psychological status. Additionally, the patients were educated about exercising the involved joints, pre-workout skin care, joint contractures, and prompt notification in case of any problems. Education on scar management, wearing and adherence to Pressure Garment (PG) was also provided. In case of noticing any serious problems during home visits, the patients were referred to a specialist (e.g. surgeon, psychologist, and physiotherapist). The duration and number of home visits were balanced against the level of needed care and problems encountered by the patient. A higher level of care and home visits were given to high-risk patients (scar, contractures, or any other serious problems). Telenursing was carried out by texting via social media, SMS, or phone calls. The frequency of the phone calls was once per week, but it increased in case of major problems or upon request.

All statistical analyses were performed using the SPSS software (version 17.0). Data were analyzed using the Chi-square test, independent t-test, and paired t-test. P<0.05 was considered statistically significant. Analysis of covariance was performed to control the effect of the frequency of home visit on the health status. To analyze the Intention to Treat (ITT) and to deal with missing data at baseline, the imputation and extreme case analyses were used.37 In the course of the observations, the last values at baseline were used instead of the missing data at 1.5 months. Additionally, the quality of the outcome of the missing data (poor or good) was also determined and analyzed.

Results

A total of 117 participants were recruited out of which 86 were included in the analysis. The number of participants in the control and intervention groups was 44 (51.2%) and 42 (48.8%), respectively. The mean burn severity in the control and intervention groups was 30.37±12.66 and 30.38±14.55, respectively. Moreover, there was no significant difference between the two groups in terms of burn severity (P=0.99). About 48% of the patients lived in rural areas. The mean number of home visits was 1.27±1.58 (1-6 times) with a duration of 20 to 105 minutes. The most common causes for attrition rate were the tendency toward traditional medicine, living in a distant rural area, financial issues, partial healing, or death. The demographic characteristics and burn details are summarized in Table 1.

All sub-scales of the BSHS-B, except simple ability and hand function, showed significant differences between the intervention and control groups after 1.5 months (P<0.05). There were significant differences between
the groups (P<0.05) in terms of the three domains of BSHS-B. (Table 2)

All sub-scales of the GHQ-28, except anxiety and insomnia, showed a significant difference between the two groups after 1.5 months (P<0.05). There was a significant difference in the VSS between the two groups (P<0.05); however, such difference was not observed in the BPI and VAS (P>0.05) (Table 3). In the intervention group, 25.5% of the patients was referred to a psychologist, 16.2% received face-to-face consultation, 6% received telephone consultation, 3.3% received both types of consultations, and 4.8% required emergency admission to a psychiatric department. The analysis of covariance showed that the number of home visits was not considered as a covariate for the BSHS-B (F (1,83)=2.39, P=0.126, η²=0.028). The result of ITT is presented in Table 4.

**DISCUSSION**

The results showed an improvement in the health status of burn patients after the intervention. A previous study in Iran also confirmed an improvement in the QOL of burn patients after a self-care education program and telephone follow-up.18 Other studies showed that rehabilitation in terms of physiotherapy,
education and occupational therapy of the patients and their families, and multimedia self-care education improved the health status of burn victims.38-40 The continuous care model can also improve the QOL of patients.41 In another study, the impact of self-care education combined with reinforcement by telephone did not have a significant effect on the intervention group.2

Unlike a study in Brazil, as the main difference, the patients in the present study suffered from deep burn injuries. It has also been shown that full thickness burns and hand injuries are strong predictors of physical QOL and continuation of pre-burn activities can improve positive post-burn qualities.42 Superficial burns are usually treated within 21 days with limited permanent

Table 2: Comparison of the scores for the Burn Specific Health Scale-Brief, domains, and sub-scales in the control and intervention groups.

| Variables                   | Control group | Intervention group | P value* (between) |
|-----------------------------|---------------|--------------------|--------------------|
|                             | Mean±SD       | Mean±SD            |                    |
| BSHS-B                      |               |                    |                    |
| Discharge                   | 61.22±19.07   | 57.14±18.92        | 0.32               |
| 1.5 month                   | 83.70±24.73   | 105.16±29.17       | <0.001             |
| P** (within)                | <0.001        | <0.001             |                    |
| Simple ability              |               |                    |                    |
| Discharge                   | 2.02±2.06     | 1.28±1.58          | 0.09               |
| 1.5 month                   | 8.45±3.29     | 9.71±3.05          | 0.09               |
| P** (within)                | <0.001        | <0.001             |                    |
| Hand function               |               |                    |                    |
| Discharge                   | 4.47±5.03     | 3.92±5.37          | 0.63               |
| 1.5 month                   | 14±4.72       | 15.97±4.79         | 0.06               |
| P** (within)                | <0.001        | <0.001             |                    |
| Affect                      |               |                    |                    |
| Discharge                   | 12.77±6.48    | 14.80±6.62         | 0.15               |
| 1.5 month                   | 15.56±7.62    | 19.34±6.87         | 0.02               |
| P** (within)                | 0.049         | 0.001              |                    |
| Interpersonal relationship  |               |                    |                    |
| Discharge                   | 8.79±3.59     | 8.52±3.61          | 0.94               |
| 1.5 month                   | 9.82±3.73     | 12.06±3.62         | 0.01               |
| P** (within)                | 0.12          | <0.001             |                    |
| Sexuality                   |               |                    |                    |
| Discharge                   | 4.25±3.57     | 2.14±1.64          | 0.001              |
| 1.5 month                   | 4.36±3.18     | 6.19±3.42          | 0.01               |
| P** (within)                | 0.46          | <0.001             |                    |
| Body image                  |               |                    |                    |
| Discharge                   | 9.70±4.28     | 10.95±4.59         | 0.19               |
| 1.5 month                   | 9.79±4.28     | 13.09±4.02         | 0.001              |
| P** (within)                | 0.12          | <0.001             |                    |
| Heat sensitivity            |               |                    |                    |
| Discharge                   | 7.38±3.91     | 5.14±3             | 0.003              |
| 1.5 month                   | 6.84±3.40     | 8.57±4.29          | 0.04               |
| P** (within)                | 0.67          | 0.007              |                    |
| Treatment regimens          |               |                    |                    |
| Discharge                   | 8.29±3.87     | 8.69±3.56          | 0.66               |
| 1.5 month                   | 9.70±3.43     | 11.71±4.61         | 0.02               |
| P** (within)                | 0.08          | <0.001             |                    |
| Work                        |               |                    |                    |
| Discharge                   | 2.36±2.22     | 2.14±2.21          | 0.65               |
| 1.5 month                   | 6.56±3.32     | 8.23±3.76          | 0.03               |
| P** (within)                | <0.001        | <0.001             |                    |
| Physical                    |               |                    |                    |
| Discharge                   | 5.54±2.31     | 4.76±2.21          | 0.11               |
| 1.5 month                   | 9.77±2.51     | 11.49±3.22         | 0.007              |
| P** (within)                | <0.001        | <0.001             |                    |
| Mental                      |               |                    |                    |
| Discharge                   | 11.23±5.09    | 12.88±5.20         | 0.14               |
| 1.5 month                   | 12.28±6.08    | 15.91±5.26         | 0.004              |
| P** (within)                | 0.18          | <0.001             |                    |
| Social                      |               |                    |                    |
| Discharge                   | 5.06±2.12     | 4.29±1.63          | 0.07               |
| 1.5 month                   | 6.78±2.30     | 8.67±3             | 0.002              |
| P** (within)                | <0.001        | <0.001             |                    |

*Independent t-test; **Paired t-test

BSHS-B: Burn Specific Health Scale-Brief
changes. Therefore, swift adaptation to the new situation is expected. It is inferred that the effect of interventions will not be as substantial in superficial burns compared to deep burns.

In the present study, the mean score of BSHS-B for the intervention group was higher than that of a study in Iran on self-care education. A study in Brazil showed that the mean score of BSHS-R was higher for both the intervention and control groups. A possible explanation is that combining education, telenursing, and home visits with direct evaluation of the burn patients during the home visit sessions may lead to an early identification of problems and timely referral to specialists (i.e. better outcomes). The difference between the studies was explained by functional independence and better QOL in the long-term.

In line with other studies, our results showed that the three domains of BSHS-B improved after the intervention. After a burn injury, the usual activities of the patient are disrupted and a potential dependency on

**Table 3:** Comparison of the physical and psychological assessments in the control and intervention groups at the time of hospital discharge and at 1.5 months post-discharge.

| Variables          | Control group                  | Intervention group             | P value* |
|--------------------|--------------------------------|--------------------------------|----------|
|                    | Mean±SD                  | Mean±SD                  |          |
| GHQ-28*            | Discharge                 | 34.38±15.68               | 0.59     |
|                    | 1.5 months                | 40.79±16.20               | <0.001   |
|                    | P value **                | 0.03                      |          |
| GHQ-sub scales     | Physical                  | 7.04±3.84                 | 0.52     |
|                    | Discharge                 | 7.61±4.40                 |          |
|                    | 1.5 months                | 8.75±4.06                 | 0.009    |
|                    | P value **                | 0.020                     |          |
|                    | Anxiety/Insomnia          | 9.93±5.15                 | 0.82     |
|                    | Discharge                 | 9.66±5.62                 |          |
|                    | 1.5 months                | 14.47±17.32               | 0.06     |
|                    | P value **                | 0.046                     |          |
|                    | Social function           | 9.13±3.54                 | 0.69     |
|                    | Discharge                 | 8.8±4.10                  |          |
|                    | 1.5 months                | 10.56±3.44                | 0.001    |
|                    | P value **                | 0.02                      |          |
|                    | Severe depression         | 8.09±6.60                 | 0.14     |
|                    | Discharge                 | 6.14±5.53                 |          |
|                    | 1.5 months                | 8.86±6.41                 | 0.002    |
|                    | P value **                | 0.51                      |          |
|                    | BPIb                      | 65.72±19.39               | 0.3      |
|                    | Discharge                 | 60.66±24.99               |          |
|                    | 1.5 months                | 21.93±29.25               | 0.31     |
|                    | P value **                | 0.001                     |          |
|                    | VSSc                      | Discharge                 | -        | 0.16    |
|                    | -                         | 6.77±3.46                 |          |
|                    | 1.5 months                | 5.16±1.68                 |          |
|                    | P value **                | 0.046                     |          |
|                    | VASd                      | Discharge                 | -        | 0.16    |
|                    | -                         | 4.20±2.88                 |          |
|                    | 1.5 months                | 4.85±3.49                 |          |
|                    | P value **                | 0.01                      |          |

*Independent t test; **Paired t-test; *General Health Questionnaire, bBrief Pain Inventory, cVancouver Scar Scale, dVisual Analogue Scale, eScar was not seen at discharge, thus the first evaluation was at 1.5 months post discharge

**Table 4:** ITT and non-ITT analysis of the randomized trial.

| Analysis                  | Intervention | Control | CI (95%)           | P value* |
|---------------------------|--------------|---------|--------------------|----------|
| ITT analysis              | Intervention | 97.55±28.79 | (9.18-28.89) | <0.001   |
| (117 subjects)            | Control      | 78.51±24.83 |          |          |
| Extreme case analysis     | Intervention | 105.22±28.16 | (14.91-37.13) | <0.001   |
|                          | Control      | 79.20±26.36 |          |          |
| Non-ITT analysis          | Intervention | 105.16±29.17 | (9.88-33.04) | <0.001   |
| (86)                      | Control      | 83.70±24.73 |          |          |

*Burn-Specific Health Scale-Brief;  †Intention to treat
others can negatively affect the perception of the patient on his/her health status. Resumption of pre-burn activities is possible by close monitoring of the health status. Rehabilitation helps the reintegration of a patient back into the workplace. Improvement in HRQOL and a better physical and psychological health were reported in patients who were involved in pre-burn activities, functions, and work after serious burn injuries.

Our results, in line with a study in China, showed that although intervention improved level of depression but the anxiety sub-scale remained an issue. In both studies, patients were evaluated at 1.5 and 3 months after intervention, which may have influenced their level of anxiety. Between 21% to 33% of burn patients are at risk of post-traumatic stress disorder at 3-6 months after burn injury. Mood and anxiety disorders, altered body image, and sleep disorder are common after burn injury. At first, depression could supposedly be reduced due to skin repair, self-care, and gaining independence. However, over time, permanent changes in appearance and social reaction to burn scars may still lead to some level of depression.

The result of the present study showed that the mean score of VSS in the intervention group was lower than that of the control group. The majority of patients used PG while the use of silicone sheets was limited to a few patients. This was also confirmed in a study, with a long-term follow-up, that showed PG therapy was effective in scar management. Early non-invasive intervention has been recommended since late scar management (i.e. >6 months after injury) leads to poor outcomes. Early identification of scar formation is possible through home visits or telenursing (sending a photo of the scar via social media). At 1.5-month, the continuity of care is essential for scar management since a successful outcome is strongly dependent on the patient’s commitment to treatment and proper usage of PG.

In comparison with a study in China, we found no significant differences in pain and itching between the two groups while itching was improved after intervention in China. This could have been due to an incomplete wound healing process causing severe pain at the time of hospital discharge. However, over time, the wound fully healed and the pain level subsided in both groups. Also, short term follow could not help to ease the itching of patients in our study.

The main strength of the present study is the uniqueness of the type of intervention (simultaneous home visit and telenursing) in Iran. Obstacles hindering the intervention were patients requiring special medical care, living in distant rural areas, inability to afford the cost of surgery, and unavailability of PG. The tendency toward traditional medicine resulted in the withdrawal of some participants, which in turn negatively impacted the study.

CONCLUSION

Health status, psychological status, and scar management were improved due to post-discharge follow-up. However, burn patients required continued care on pain, psychological health, and itching problems. A follow-up over a longer period is recommended to achieve better outcomes.

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