Effects of A Nurse-Led Transitional Burns Rehabilitation Programme (4Cs-TBuRP) For Adult Burn Survivors: Protocol for a Randomised Control Trial

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Abstract

Background: Transitioning from the burn unit to the home/ community can be chaotic with limited professional support. Some adult burn survivors may face varied concerns leading to poor outcomes in the early post-discharge period with limited access to professional help. Based on these, a nurse-led transitional burns rehabilitation programme has been developed and the current trial aims to ascertain its effects as well as explore the implementation process.

Methods: A single-centre, double-arm randomised controlled trial with a process evaluation phase will be utilised for this study. All adult burn survivors aged ≥18 years with burn size ≥10% total burn surface area at the site during the study period will be screened for eligibility at least 72hours to discharge. A sample size of 150 will be block randomised to treatment (receiving the nurse-led transitional care programme and routine post-discharge service) and control groups (receiving routine post-discharge service). The nurse-led transitional care programme comprises of predischarge and follow-up phases with the delivery of bundle of holistic interventions lasting for 8 weeks. There are three timelines for data collection: baseline, immediate post-intervention, 4 weeks post-intervention.

Discussion: The findings from this study can potentially inform the development and organisation of post-discharge care and affirm the need for ongoing comprehensive home-based care for burn survivors and their families.

Trial registration: ClinicalTrials.gov Trial Registry approved the prospective registration on 20 th August 2020. Registration details can be viewed on https://clinicaltrials.gov/ct2/show/record/NCT04517721 .

Background And Rationale

Burns are one of the most devastating forms of injuries that primarily affect the skin (1). Depending on the extent of the injury, a burned patient may require critical care to resolve physiological alterations. As care progresses during emergent/ acute phase, rehabilitation that occurs concurrently can promote recovery (2-4). Rehabilitation minimizes the adverse consequences of the burn by improving functional ability, enhancing psychological well-being, facilitating early return to work/ school and improving quality of life (5). As rehabilitation occurs, the burn patient is able to attain a degree of pre-injury abilities as closely as possible (6, 7), and is able to do things that are desirable to them as recover progresses (8, 9).

Along the recovery trajectory for burn survivors, previous studies have observed that the greatest physical and psychosocial decline may be experienced following discharge (10-12). Concerns regarding pain, anxiety, and uncertainties about return to work/ community integration may emerge immediately following discharge (13, 14). By 2-3 months post-discharge, burn survivors may experience increasing depression/ anxiety levels, itchiness associated with healed wounds, pain, poor sleep, scarring, and difficulties with physical functioning/ performance leading to poor quality of life in the absence of rehabilitative support commensurate to their needs (13, 15, 16). By 6-12 months post-discharge, the burn survivor may experience further distress reflected by the high rates of depression, sleep disturbances,

body image concerns and posttraumatic stress disorder (16-18). Taken together, these may suggest that the transitional period from the immediate pre-discharge to the early post-discharge phase represent a vulnerable stage which can impact long-term recovery outcome (14).

Despite the emergence of varied needs following discharge, there is often limited communication, lack of coordinated and continuous professional support as the burn patient transits from hospital to the home/ community (13, 14, 19). Home care and support may become chaotic, often with limited access to professional support. Some burn survivors may not also return to the hospital for follow-up care due to long travel distances and associated costs. Comprehensive follow-up system of care in the home/ community is therefore greatly needed to promote rehabilitation of burn survivors (20). It is worth mentioning that the home/ community has been identified as a suitable location for the implementation of burn rehabilitation programmes which can enhance patient outcomes, particularly if the programme is structured and have active follow ups on the burn survivor (21). Thus, to bridge the immediate pre-discharge and early post-discharge gap and improve patient outcomes, a nurse-led transitional burns rehabilitation programme (4Cs-TBuRP) has been developed following the Medical Research Council (MRC) Framework (22).

Developing the intervention proceeded through extensive literature reviews, exploratory studies, and expert consultations. The current phase seeks to evaluate the effectiveness of the programme in comparison to the existing standard of care. The 4Cs in the intervention represent comprehensiveness, coordination, collaboration, and continuity, which were proven to be essential transitional care elements tested among patients with chronic conditions (23-25). The 4Cs emphasise on the need for ongoing holistic care required by burn survivors throughout the recovery trajectory. We hypothesize that the nurse-led transitional rehabilitation programme underpinned by multi-disciplinary support is helpful to ensure continuity of care in a comprehensive and coordinated manner and lead to improved patient outcomes in the early post-discharge period. This study protocol was completed in accordance with the SPIRIT 2013 guidelines (26).

Objectives

The trial will explore the effects and implementation process of a nurse-led transitional rehabilitation programme for adult burn survivors. Primarily, we seek to evaluate the effects of a nurse-led transitional rehabilitation programme on quality-of-life psychological functioning, sleep patterns, itchiness, pain, and physical role functioning/ performance among adult burn survivors. A secondary objective of this study is to examine the process involved and issues encountered during the implementation of the transitional rehabilitation programme.

Trial design

The trial is a double-arm (intervention and control groups), single-centre randomised controlled trial with 1:1 allocation ratio and a follow-up process evaluation phase. We will firstly undertake a pilot feasibility phase and follow-up with the full-scale trial. The null hypothesis is that there will be no difference

regarding outcomes between the intervention and control groups. The alternative hypothesis is that there will be statistically significant differences between the participants undergoing the nurse-led programme of care and participants receiving the existing standard of care. The follow-up process evaluation phase will employ qualitative methods to examine the process and issues during the implementation process.

Methods (Participants, Interventions, And Outcomes)

Study setting

This single-centre trial will be conducted at the Gansu Provincial Hospital, Lanzhou, People's Republic of China. The hospital is a comprehensive top-ranked 3A facility integrating medical services with teaching, research, and preventive care. The facility was established in 1950 and is in the Northwestern part of China. The hospital currently has a total of 3370 beds across various medical and surgical specialties with outpatient facilities.

Eligibility Criteria

All burn survivors receiving burn care services at the study site will be screened for eligibility during the study period. Adult burn survivors aged ≥18 years with burn size ≥10% TBSA as assessed by the burn surgeon/ burn care nurse (irrespective of the depth of the burn), absence of a confirmed psychiatry condition, renal failure, or diabetes mellitus and reachable on phone and WeChat will be considered for inclusion. Adult burn survivors who are unable to communicate or are enrolled in another rehabilitation trial will be excluded. Participants for the follow-up process evaluation phase will be recruited from both arms of the trial. The intervention will be primarily provided and coordinated by a Burn Care Nurse with referrals to other members of the multi-disciplinary burns team. Burn care nurses recruited to deliver the intervention will have at least 4 years working experience in the burn unit at the study site and must complete a mandatory training programme which covers contents of the comprehensive transitional care program for burn patients with theory and practice (18 hours in total) and passed a competence test prior to participating in the study.

Intervention

Eligible participants will be randomised to either the treatment or control group. Participants in the control group will continue to utilise the existing service at the hospital in addition to two social calls by a trained student nurse. Participants in the treatment group will receive the nurse-led transitional burns rehabilitation programme (4Cs-TBuRP) in addition to existing service at the hospital. There are two phases to the 4Cs-TBRP:

- **Phase 1 (Discharge planning/ preparation):** This phase will take place at least 72 hours prior to the day of discharge. Guided by the Omaha System, a comprehensive patient assessment based on a care plan covering environmental, physiological, psychosocial, and health-related behaviour domains will be carried out (27). The bundle of interventions available is based on the identified need which

include environmental (health education to improve sanitation and environmental hygiene within residence); physiological (pain management, itch management, comprehensive scar management, range of motion activities, management of heat sensitivity, skin care, nutritional assessment/ support, infection prevention and control measures); psychosocial (social skills training, counseling care, health education, positive reinforcement, spiritual care, meditation, and music therapy); and health-related behaviour (strategies to improve sleep/ rest, physical therapy, and participation in activities of daily living).

- **Phase 2 (Follow-up Phase):** This phase comprises of 2 structured WeChat telehealth, 6 structured telephone follow-ups and daytime patient/ family-initiated telephone service over an 8-week period. Like the discharge planning phase, care planning and intervention are undertaken using the Omaha System as a guide for the 8-week period. The bundle of interventions available based on the identified need/ domain include environmental (health education to improve sanitation and environmental hygiene within residence); physiological (pain management, itch management, comprehensive scar management, range of motion activities, management of heat sensitivity, skin care, nutritional assessment/ support, infection prevention and control measures); psychosocial (social skills training, counseling care, health education, positive reinforcement, spiritual care, meditation, music therapy and aromatherapy); and health-related behaviour (strategies to improve sleep/ rest, physical therapy, and participation in activities of daily living). Where referrals are required, a referral form will be completed for the service to be provided. Home visits will be carried out if the adult burn survivor has concerns which can best be handled face to face by the nurse (example: assistance with wound care or reinforcing scar management education).

Strategies to improve adherence/ fidelity of the intervention

Fidelity will be ensured in this study by using the guidelines offered by Bellg et al.(28) which comprises of 1) ensuring that the intervention dose is the same for all participants across each condition, (2) standardizing interventionist training, (3) monitoring the intervention delivery, (4) evaluating participants' understanding of information provided, and (5) ensuring that participants use the skills taught in the intervention. Adherence reminders will also be given every week to participants during the follow-up via WeChat or telephone.

Study outcomes

Primary outcome

Quality of life: Quality of life which is defined as the adult burn survivors' perceptions of their health status and well-being is the primary outcome for the trial and will be assessed at baseline (T0), following completion of the intervention at 8 weeks (T1) and at 4 weeks post-intervention (T2). The outcome will be objectively assessed using the Chinese version of the Burn Specific Health Scale-Brief and EQ-5D-5L. The BSHS is an outcome scale designed specifically for burns patients. It comprises of four areas: physical, psychological, social relations and general health condition, that is consistent with the biopsychosocial

model. A recent review has suggested that generic scales are more sensitive than the BSHS-B domains from one-month post-burn (29). Thus, as the study will cover up to three months post-discharge, the BSHS-B and EQ-5D will be used to measure quality of life in the study. The BSHS-B comprises of 40 questions, 9 sub-scales, and 3 domains (physical, mental, and social). Internal consistency of the total instrument has been reported to be α=0.94 with test-retest reliability suggesting that the Intraclass Correlation Coefficient (ICC) ranged from 0.81 to 0.96 with a total score of 0.93 (30). The Chinese version has 38 items with a reported Cronbach alpha 0.97 and split half reliability of 0.98 (31). The EQ-5D-5L is a generic tool to assess quality of life. The instrument has five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The EQ-5D-5L is a valid extension of the 3-level system (EQ-5D-3L) which is found to have improved measurement properties, with reduced ceiling effect, strengthened discriminatory power and established convergent and known-groups validity (32).

Secondary outcomes

Assessment of secondary outcomes will also commence at baseline T0 (recruitment to the study), following completion of the intervention at 8 weeks (T1) and at 4 weeks post-intervention (T2):

Psychological functioning: The Chinese version of the Hospital Anxiety and Depression Scale (HADS) will be used to evaluate psychological functioning (anxiety and depression). The 14-item *HADS* was designed as a tool to screen for anxiety and depressive symptoms in medical settings, and has well-demonstrated solid psychometric properties for use in medical settings (33-35) and commonly used in burn care settings to screen anxiety and depression (36).

Sleep pattern improvement: The Chinese version of the Pittsburgh Sleep Quality Index (PSQI) will be used to evaluate sleep improvement. It includes 19 items with a total score that ranges from 0 to 21. A higher PSQI score implies poorer quality of sleep (37). In general, a PSQI score greater than 5 is considered to indicate poor sleep quality (37).

Pain: The Chinese version of the Brief Pain Inventory will be used to evaluate pain among participants. 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 (38).

Itch: The Chinese version of a visual analogue scale (VAS) will be used to evaluate this outcome among participants. The VAS has been observed to have an intraclass correlation coefficient of 0.88 (39).

Physical role functioning/ performance: The Chinese version of the Disability of the Arm, Shoulder and Hand Symptom Scale (DASH) will be used to evaluate this outcome (40). The DASH tool is a 30-item questionnaire that asks the patient to grade symptoms and physical function during the preceding week

on a five-point Likert scale. The reliability of the DASH is excellent (intraclass correlation coefficient 0.97 with Cronbach's alpha of 0.97) (40).

Scarring: The Vancouver Scar Scale (VSS) will be used to assess this outcome in the current study. The VSS is a validated subjective tool that assesses vascularity, pigmentation, pliability, and height of scars (41). The tool remains the main tool used to evaluate scarring in burn care research (41). The total score ranges from 0-13 with lower scores implying improved scars.

Participant timeline

Participants will be assessed for eligibility and enrolled to the study 72 hours to discharge from the burn unit. Baseline data collection with a battery of outcome measures along with demographic data. The intervention commences for participants in the treatment group with the pre-discharge component of the programme of care. Weekly follow-ups will be conducted by the nurse case managers. The second phase of data collection will be completed by 8 weeks post-intervention. Follow-up data will be obtained at 4 weeks following the second data collection phase (see figure 2).

Sampling and Sample size estimation

Purposive sampling will be used to recruit adult burn survivors with burn size ≥10% TBSA from the Burn Unit. Upon recruitment, randomisation to either control or treatment group (ratio 1:1) with a blinded approach will be carried out. For the pilot phase of the project, the pilot feasibility sample size rule suggested by Whitehead, Julius, Cooper, & Campbell will be used (42). The rule specifies that a total sample size of 25 participants per arm. Considering possible attrition rate of 20% that has been reported in burn care literature implies that an additional 5 participants will be added to both arms summing up to 30 participants per arm (total = 60 participants).

For the main trial, the sample size calculation based on the primary outcome measure (Burn Specific Health Scale) at 95% confidence level and 90% statistical power will yield a total of 38 participants per arm (43, 44). Considering an attrition rate of 20%, the final sample size will be 45 participants per arm (total = 90 participants). In all, 150 participants will be recruited for the entire study. For the follow-up process evaluation phase, we will conveniently recruit up to fifteen (15) participants from each arm whilst being guided by the principle of data saturation.

Recruitment

A research nurse at the study site will identify potential subjects' eligibility for enrolment in the study based on the inclusion and exclusion criteria described above. All participants will be enrolled/ recruited by a Registered Nurse (RN-1) who will not be involved in the delivery of the intervention or outcome assessment (see figure 1). RN-1 will follow-up on patient's case notes on daily basis to ascertain if any adult burn survivor has a pending discharge status. If pending discharge is noted, RN-1 will check if the adult burn survivor fulfils the criteria for inclusion; if so, the patient will be invited to participate. Details of the study will be made known and information sheet duly explained. Thereafter, RN-1 will ensure that two

consent forms (covering both outcome and process evaluation phases) are signed, or thumb printed by the adult burn survivor which will then be forwarded to a research assistant (RA) who will complete the baseline assessment. A research team member (RTM) who is not involved in clinical services and have no knowledge about the potential subjects will take over from this phase and proceed to work on randomisation and allocation. The subjects allocated to the intervention arm will be referred to the nurse case manager to commence the intervention. Following the exit of participants from the intervention, they will be contacted and invited to participate in the process evaluation phase.

Methods (Assignment of intervention)

Randomisation and Allocation

Prior blocked randomisation list with 75 sets of numbers will be generated using the Research Randomizer. As soon as the consent form is received, the RTM will sequentially open the sealed envelopes containing the paper with the number assignment and unfold it. The number written specifies the group to which the adult burn survivor will be allocated. The allocation sequence will be concealed to RN-1 and the research assistant (RA) to minimise bias in the study.

Blinding

Following recruitment, any possible identifying material that could indicate to the blinded assessors, which group a participant was allocated to, will be removed. Participants will not be blinded as to the group they have been assigned to. Additionally, it will not be possible to blind the interventionists, that is, the burn care nurses who will deliver the intervention only to participants in the treatment group.

Data collection, Management and Analysis

Data collection methods and management

All outcomes will be assessed at baseline (T0), that is after the patient has been recruited. Following the completion of the intervention, the second phase of data collection (T1) will be undertaken, that is at the 8th week. The third phase of data collection (T2) will be the follow-up phase at 4 weeks post-intervention. Data collection will be in the form of completion of questionnaires. The data collection process will be undertaken by three research assistants who will be blinded to the groups of the participants. The research assistants have completed a 10-hour training programme covering the outcome measures to be used. Following the training, they undertook a role play to enable the research team ascertain the inter-rater reliability/ percentage agreement with the following results: Burn Specific Health Scale-B (87.7%), EQ-5D-5L (100%), HADS (92.5%), PSQI (86.7%), DASH (84.4%), VAS (100%), BPI (100%) and VSS (100%). All quantitative data will be entered and stored in SPSS Version 25 (SPSS, an IBM company, Chicago, Illinois, USA). All hard copies of documents relating to the study will be stored under lock and key only accessible to designated research team member.

For the follow-up process evaluation phase, face to face semi-structured interviews with an interview guide will be utilised to collect data after the intervention period has elapsed. All interview proceedings will be audiotaped and transcribed verbatim in the Trint Automated Transcription Software. Interview transcripts will be exported to QSR NVivo version 10 will be used to manage the data. All soft files related to the study will be kept in a password protected computer only accessible to the principal investigator and the doctoral student investigator. Paper files will be kept under lock and key.

Statistical Methods and Analysis

The data analysis plan will proceed through data entry and cleaning, missing data management and statistical analysis. All quantitative data will be coded and entered to SPSS Version 25 (SPSS, an IBM company, Chicago, Illinois, USA). The data will be inspected visually with random searches and frequency counts to ascertain its completeness. Demographic and clinical characteristics will be compared using chi square test (for normally distributed data) or Mann Whitney U test (data that is not normally distributed). Between group differences will be assessed using independent t test (for continuous data). Both per-protocol (PP) and intention to treat analysis (ITT) will be performed respectively on participants who completed the entire intervention and those recruited to participate. Methods for longitudinal data such as generalized estimating equations (GEE) will be employed. All statistical tests will be conducted at 95% confidence interval.

Qualitative data emerging from the follow-up process evaluation phase will be analyzed using content analysis. All audio recordings will be transcribed verbatim and translated from Chinese to English using the Trint Automation Software. The transcripts will be inspected for correctness and completeness by two native speakers who are also fluent in English. The final versions will be exported to the NVivo version 10 software. In the early stage of analysis, a broad question will be posed to grasp the whole picture. As analysis progresses, the researcher will go beyond the initial theoretical scaffolding to develop an understanding and interpretation of the data (45).

Monitoring

Minimal adverse effects are expected from the proposed intervention. Standardised protocols exist at the study centre regarding the management of known of potential adverse effects such as infection. Adverse events related to the intervention will be monitored through review of the patient's records, participant self-report and by the clinicians. All adverse events will be reported to the Institutional Review Board of the Hong Kong Polytechnic University.

Ethics and dissemination

Ethical clearance for the study has been granted by the Institutional Review Board of the Hong Kong Polytechnic University (HSEARS20200730001). Additionally, the study has been prospectively registered with a trial registry and currently available in public domain (NCT04517721). The IRB and trial registry will be informed of any modifications that may occur during the conduct of the trial. Consent will be

obtained from participants before completing the recruitment process. All data emerging from the studies will be kept under lock kept by authorized personnel. Confidentiality and anonymity will be ensured throughout the study. Data emerging from the study will be accessed only by the research and clinical teams. Trial auditing will be conducted every six weeks. The investigators plan to disseminate the trial results via publication in peer reviewed journals and at conferences. All research and clinical team members meeting authorship criteria will have final authority over manuscript content. The study protocol, if published, will be available in public domain. However, participant-level dataset will be maintained by the research/ team which can be made available on reasonable request.

Discussion

Recovery following burns is a complex process with varied biopsychosocial-environmental needs and rehabilitative support commensurate to those needs is very important to ensure optimal recovery of the burn survivors (46). Recent studies have likened the recovery process following burns to living with a chronic ailment which suggest that a flexible but structured and sustained follow-up plan is required to support the burn survivor and their families (47, 48). Transitioning from the Burn Unit to the home/ community is often chaotic with burn survivors and their families experiencing limited professional support (48, 49). A lack of continuous and comprehensive support in the early post-discharge period adversely affects patient outcomes, thus creating a critical gap.

The concept of rehabilitation is still under development in most parts of Mainland China (4, 50-52). The escalating chronic disease burden and ageing population further leaves limited resources allocated to burns rehabilitation in Mainland China (52). Previous studies in Mainland China have highlighted the significant focus on medical management of burn injuries with limited attention to comprehensive rehabilitative support (4, 50). Thus, service gaps may exist to offer comprehensive rehabilitative support to burn survivors. Meeting this need requires multidisciplinary efforts to ensure that burn survivors and their families receive professional support commensurate to their needs in a continuous and coordinated manner. The nurse-led transitional burns rehabilitation programme (4Cs-TBuRP) will add new knowledge regarding the organization and implementation of professional support for adult burn survivors and their families as well as strengthening post-discharge care at the study hospital. The programme extends the function of burn care nurses into advanced roles regarding coordinating care and delivering advanced burn care support such as scar management in home-based environment. Additionally, the follow-up process evaluation phase will offer insights into the implementation process to understand contextual factors that facilitated or hindered the delivery of the intervention. By combining quantitative and qualitative data, we will attain greater explanatory power and move beyond 'does it work?' to 'what works and for who?'. Based on past trials, an anticipated limitation of this study may be dropout rate. Possible attrition bias will be addressed by examining the extent and reasons for dropout across the intervention and control groups.

In conclusion, the 4Cs-TBuRP offers an opportunity to actively follow up on burn survivors and their families following discharge and offer professional support within the home environment. This is in

response to a global need for continued rehabilitative care for burn survivors following discharge (14). The telehealth component which reflects the changing nature of healthcare particularly as the world is still navigating through the coronavirus pandemic implies that burn survivors will continue to receive professional support at a distance highlighting the potential benefits of the 4Cs-TBuRP (53, 54).

Declarations

Trial status

Recruitment is expected to commence in November 2020 and intended completion date is December 2022.

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Availability of data and materials

Not applicable

Authors' contribution

JB, FKYW and LCYF worked together from study conceptualization, writing up, critical review and approval for publication.

Ethics approval and consent to participate

Ethics for the study has been granted by the Hong Kong Polytechnic University (HSEARS20200730001). The trial is prospectively registered with ClinicalTrials.gov registry (NCT04517721). Consent to participate will be obtained from all eligible participants before commencing the intervention.

Consent for publication

Not applicable

Competing interests

The authors declare no competing interests.

Protocol version: Protocol amendment number 2. Amendment 01 (17/08/2020): Proper use of title case formats, removal of all in-text references, change in the study type and report on the maximum and minimum scores of all outcome measures.

Trial sponsor: The Hong Kong Polytechnic University

Role of sponsor: The trial sponsor had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

References

1. Stylianou N, Buchan I, Dunn KW. A review of the international Burn Injury Database (iBID) for England and Wales: descriptive analysis of burn injuries 2003–2011. BMJ open. 2015;5(2).
2. Flores O, Tyack Z, Stockton K, Paratz JD. The use of exercise in burns rehabilitation: A worldwide survey of practice. Burns. 2020;46(2):322–32.
3. Procter F. Rehabilitation of the burn patient. Indian journal of plastic surgery: official publication of the Association of Plastic Surgeons of India. 2010;43(Suppl):101.
4. Tang D, Li-Tsang CW, Au RK, Li K-c, Yi X-f, Liao L-r, et al. Functional outcomes of burn patients with or without rehabilitation in mainland China. Hong Kong journal of occupational therapy. 2015;26(1):15–23.
5. Cen Y, Chai J, Chen H, Chen J, Guo G, Han C, et al. Guidelines for burn rehabilitation in China. Burns trauma. 2015;3:1–10.
6. Hundeshagen G, Suman OE, Branski LK. Rehabilitation in the acute versus outpatient setting. Clin Plast Surg. 2017;44(4):729–35.
7. Young AW, Dewey WS, King BT. Rehabilitation of burn injuries: an update. Phys Med Rehabil Clin North Am. 2019;30(1):111–32.
8. Gerber LH, Bush H, Holavanahalli R, Esselman P, Schneider J, Heinemann A, et al. A scoping review of burn rehabilitation publications incorporating functional outcomes. Burns. 2019;45(5):1005–13.
9. Kornhaber R, Rickard G, McLean L, Wiechula R, Lopez V, Cleary M. Burn care and rehabilitation in Australia: health professionals' perspectives. Disabil Rehabil. 2019;41(6):714–9.
10. Askay SW, Stricklin M, Carrougher GJ, Patterson DR, Klein MB, Esselman PC, et al. Using QMethodology to identify reasons for distress in burn survivors postdischarge. Journal of burn care research. 2009;30(1):83–91.
11. HeydariKhayat N, Ashktorab T, Rohani C. Home care for burn survivors: A phenomenological study of lived experiences. Home Health Care Services Quarterly. 2020:1–14.
12. Wasiak J, Paul E, Lee SJ, Mahar P, Pfitzer B, Spinks A, et al. Patterns of recovery over 12 months following a burn injury in Australia. Injury. 2014;45(9):1459–64.
13. Christiaens W, Van de Walle E, Devresse S, Van Halewyck D, Benahmed N, Paulus D, et al. The view of severely burned patients and healthcare professionals on the blind spots in the aftercare process: a

qualitative study. BMC Health Serv Res. 2015;15(1):1–11.

14. Herzog AP, Grzelak CR, editors. Implementing a Transitional Care Model between Healthcare Settings for Patients with Complex Burn Injuries. APTA; 2020. 2020 Combined Sections Meeting (CSM).

15. Echevarría-Guanilo M, Gonçalves N, Farina J, Rossi L. Assessment of health-related quality of life in the first year after burn. Escola Anna Nery-Revista de Enfermagem. 2016;20(1):155–66.

16. Van Loey NE, Van Son MJ. Psychopathology and psychological problems in patients with burn scars. American journal of clinical dermatology. 2003;4(4):245–72.

17. McAleavey AA, Wyka K, Peskin M, Difede J. Physical, functional, and psychosocial recovery from burn injury are related and their relationship changes over time: A Burn Model System study. Burns. 2018;44(4):793–9.

18. Wiechman SA, McMullen K, Carrougher GJ, Fauerbach JA, Ryan CM, Herndon DN, et al. Reasons for distress among burn survivors at 6, 12, and 24 months postdischarge: a burn injury model system investigation. Arch Phys Med Rehabil. 2018;99(7):1311–7.

19. Serghiou M, Niszczak J, Parry I, Li-Tsang C, Van den Kerckhove E, Smailes S, et al. One world one burn rehabilitation standard. Burns. 2016;42(5):1047–58.

20. Jagnoor J, Lukaszyk C, Christou A, Potokar T, Chamania S, Ivers R. Where to from here? A quality improvement project investigating burns treatment and rehabilitation practices in India. BMC Res Notes. 2018;11(1):224.

21. Bayuo J, Wong FKY. Intervention content and outcomes of post-discharge rehabilitation programmes for adults surviving major burns: a systematic scoping review. Journal of Burn Care & Research. 2020.

22. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337.

23. Wong FKY, Chow SKY, Chan TMF. Evaluation of a nurse-led disease management programme for chronic kidney disease: a randomized controlled trial. International journal of nursing studies. 2010;47(3):268–78.

24. Wong FKY, Mok MPH, Chan T, Tsang MW. Nurse follow-up of patients with diabetes: randomized controlled trial. Journal of advanced nursing. 2005;50(4):391–402.

25. Wong FKY, Ng AYM, Lee PH, Lam P-t, Ng JSC, Ng NHY, et al. Effects of a transitional palliative care model on patients with end-stage heart failure: a randomised controlled trial. Heart. 2016;102(14):1100–8.

26. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200–7.

27. Martin KS, Monsen KA, Bowles KH. The Omaha system and meaningful use: applications for practice, education, and research. CIN: Computers Informatics Nursing. 2011;29(1):52–8.

28. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change

Consortium. Health Psychol. 2004;23(5):443.

29. Spronk I, Legemate C, Oen I, van Loey N, Polinder S, van Baar M. Health related quality of life in adults after burn injuries: a systematic review. PLoS One. 2018;13(5):e0197507.

30. Pishnamazi Z, Rejeh N, Heravi-Karimooi M, Vaismoradi M. Validation of the Persian version of the Burn Specific Health Scale–brief. Burns. 2013;39(1):162–7.

31. Ling-Juan Z, Jie C, Jian L, Xiao-Ying L, Ping F, Zhao-Fan X, et al. Development of quality of life scale in Chinese burn patients: Cross-cultural adaptation process of burn-specific health scale–brief. Burns. 2012;38(8):1216–23.

32. Janssen M, Pickard AS, Golicki D, Gudex C, Niewada M, Scalone L, et al. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. Qual Life Res. 2013;22(7):1717–27.

33. Cameron IM, Crawford JR, Lawton K, Reid IC. Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. Br J Gen Pract. 2008;58(546):32–6.

34. Cameron IM, Crawford JR, Lawton K, Sharma S, Dutoit S, Hay S, et al. Assessing the validity of the PHQ-9, HADS, BDI-II and OIDS-SR$_{16}$ in measuring severity of depression in a UK sample of primary care patients with a diagnosis of depression: Study protocol. Primary Care & Community Psychiatry; 2008.

35. Roberts SB, Bonnici DM, Mackinnon AJ, Worcester MC. Psychometric evaluation of the Hospital Anxiety and Depression Scale (HADS) among female cardiac patients. Br J Health Psychol. 2001;6(4):373–83.

36. Tedstone JE, Tarrier N. An investigation of the prevalence of psychological morbidity in burn-injured patients. Burns. 1997;23(7–8):550–4.

37. Tsai P-S, Wang S-Y, Wang M-Y, Su C-T, Yang T-T, Huang C-J, et al. Psychometric evaluation of the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI) in primary insomnia and control subjects. Qual Life Res. 2005;14(8):1943–52.

38. Ger L-P, Ho S-T, Sun W-Z, Wang M-S, Cleeland CS. Validation of the Brief Pain Inventory in a Taiwanese population. J Pain Symptom Manag. 1999;18(5):316–22.

39. Reich A, Heisig M, Phan NQ, Taneda K, Takamori K, Takeuchi S, et al. Visual analogue scale: evaluation of the instrument for the assessment of pruritus. Acta dermato-venereologica. 2012;92(5):497–501.

40. Lee EW, Lau JS, Chung MM, Li AP, Lo SK. Evaluation of the Chinese version of the Disability of the Arm, Shoulder and Hand (DASH-HKPWH): cross-cultural adaptation process, internal consistency and reliability study. Journal of hand therapy. 2004;17(4):417–23.

41. Fearmonti R, Bond J, Erdmann D, Levinson H. A review of scar scales and scar measuring devices. Eplasty. 2010;10.

42. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a

continuous outcome variable. Stat Methods Med Res. 2016;25(3):1057–73.

43. Heydarikhayat N, Ashktorab T, Rohani C, Zayeri F. Effect of post-hospital discharge follow-up on health status in patients with burn injuries: a randomized clinical trial. International journal of community based nursing midwifery. 2018;6(4):293.

44. Kildal M, Andersson G, Fugl-Meyer AR, Lannerstam K, Gerdin B. Development of a brief version of the Burn Specific Health Scale (BSHS-B). Journal of Trauma Acute Care Surgery. 2001;51(4):740–6.

45. Hunt MR. Strengths and challenges in the use of interpretive description: reflections arising from a study of the moral experience of health professionals in humanitarian work. Qual Health Res. 2009;19(9):1284–92.

46. Bayuo J, Wong FKY, Agyei FB. "On the Recovery Journey:" An Integrative Review of the Needs of Burn Patients From Immediate Pre-Discharge to Post-Discharge Period Using the Omaha System. Journal of nursing scholarship. 2020.

47. Barrett LW, Fear VS, Waithman JC, Wood FM, Fear MW. Understanding acute burn injury as a chronic disease. Burns & trauma. 2019;7:s41038-019-0163-2..

48. Litchfield I, Jones LL, Moiemen N, Andrews N, Greenfield S, Mathers J. The role of self-management in burns aftercare: a qualitative research study. Burns. 2019;45(4):825–34.

49. Van den Heede K, Dubois C, Mistiaen P, Stordeur S, Cordon A, Farfan-Portet MI. Evaluating the need to reform the organisation of care for major trauma patients in Belgium: an analysis of administrative databases. Eur J Trauma Emerg Surg. 2019;45(5):885–92.

50. Chen J, Li-Tsang CW, Yan H, Liang G, Tan J, Yang S, et al. A survey on the current status of burn rehabilitation services in China. Burns. 2013;39(2):269–78.

51. Tang D, Li-Tsang CW, Au RK, Shen X, Li K-c, Yi X-f, et al. Predictors of functional independence, quality of life, and return to work in patients with burn injuries in mainland China. Burns & trauma. 2016;4.

52. Xiao Y, Zhao K, Ma Z-X, Li X, Qiu Y-P. Integrated medical rehabilitation delivery in China. Chronic Diseases Translational Medicine. 2017;3(2):75–81.

53. Barret JP, Chong SJ, Depetris N, Fisher MD, Luo G, Moiemen N, et al. Burn center function during the COVID-19 pandemic: An international multi-center report of strategy and experience. Burns. 2020;46(5):1021–35.

54. Sharaf A, Muthayya P. Multidisciplinary management of the burn injured patient during a pandemic-The role of telemedicine. Burns. 2020.
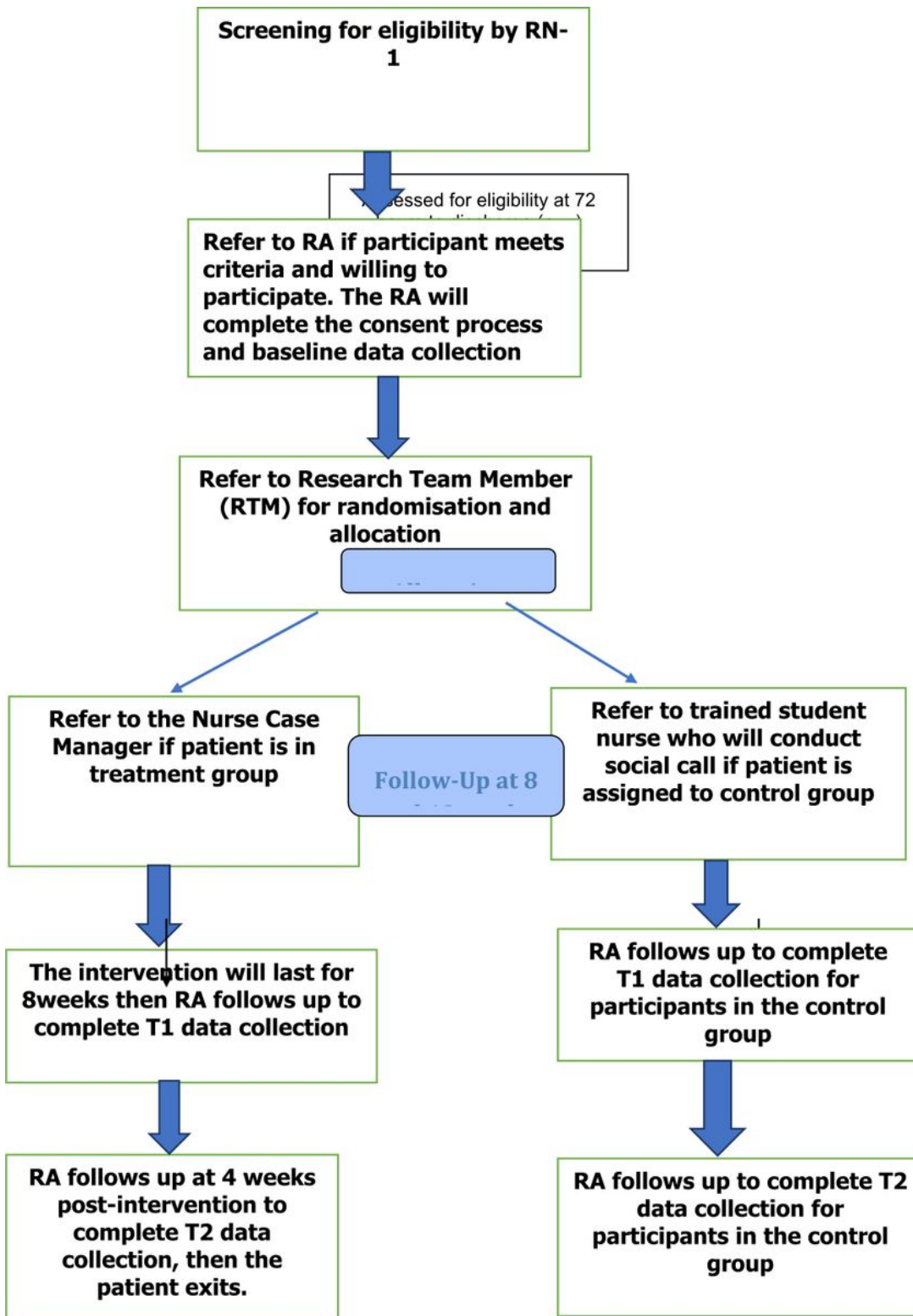
Figures

Screening for eligibility by RN-1

↓

Refer to RA if participant meets criteria and willing to participate. The RA will complete the consent process and baseline data collection

↓

Refer to Research Team Member (RTM) for randomisation and allocation

↙ ↘

Refer to the Nurse Case Manager if patient is in treatment group

Follow-Up at 8

Refer to trained student nurse who will conduct social call if patient is assigned to control group

↓

The intervention will last for 8weeks then RA follows up to complete T1 data collection

RA follows up to complete T1 data collection for participants in the control group

↓

RA follows up at 4 weeks post-intervention to complete T2 data collection, then the patient exits.

RA follows up to complete T2 data collection for participants in the control group
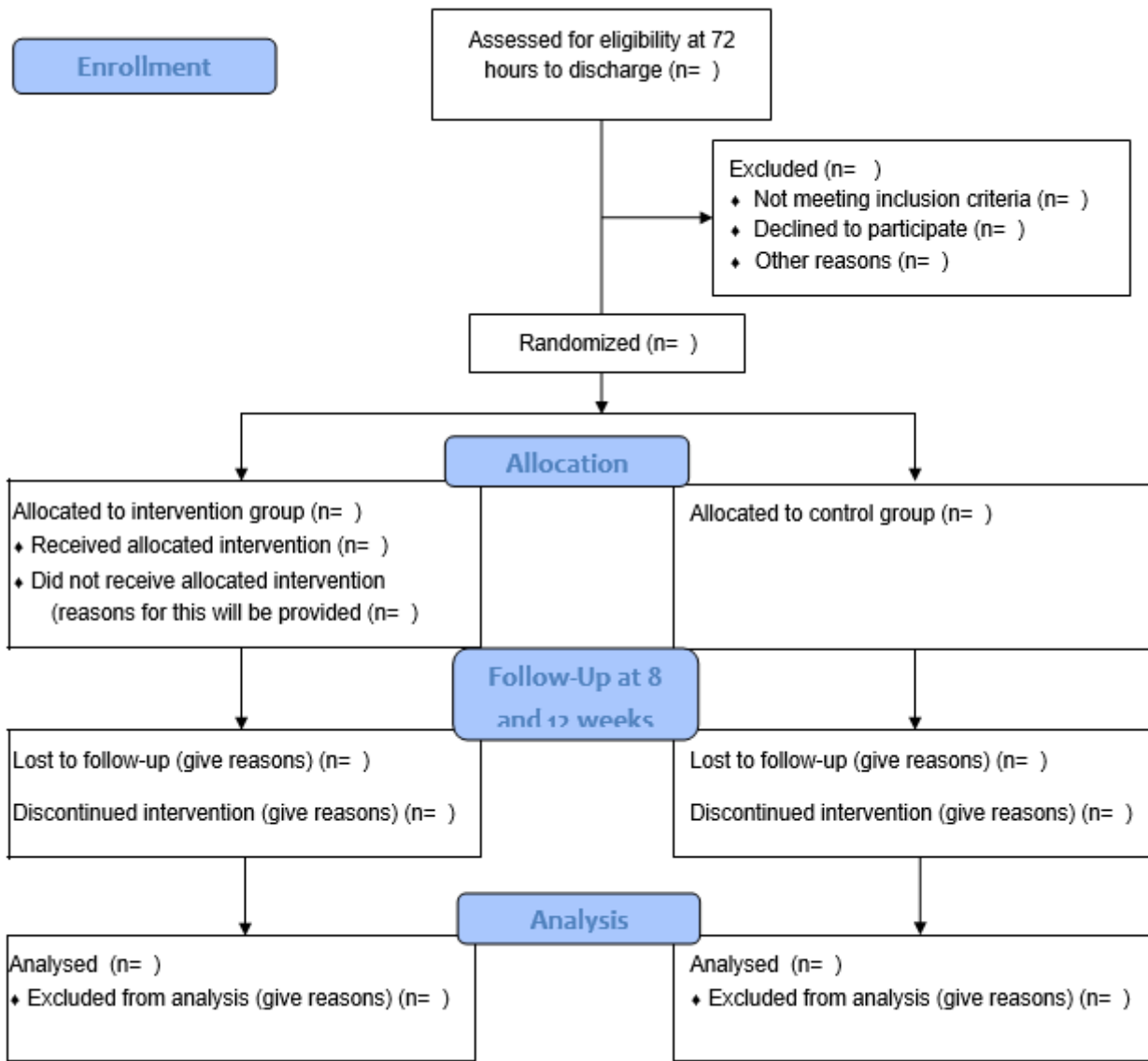
Figure 1

CONSORT 2010 Flow Diagram

Figure 2

Data Collection Flowchart

Supplementary Files

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- SPIRITChecklist19Apr21.doc