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Effectiveness of mHealth interventions to improve follow-up care and management among solid organ transplant recipients: a systematic review protocol

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Risk of bias assessment.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 August 2024 and was last updated on 22 August 2024.

INTRODUCTION

Review question / Objective 1. To identify the current forms of mHealth technologies utilized and implemented in the follow-up care and management of the solid organ transplant recipients. 2. To evaluate the impact and effectiveness of mHealth interventions in the follow-up and management of solid organ transplant recipients, including aspects such as immunosuppressant management, exercise management, nutritional management, home monitoring, complication prevention and control, and outpatient visits, etc. 3. To determine the satisfaction and acceptance of mHealth technologies among solid organ transplant recipients.

Rationale Some studies have investigated the application of mHealth technology in different facets of post-transplant follow-up management. However, the findings of these studies are markedly inconsistent. While some studies have demonstrated a significant impact of mHealth interventions, other studies have reported no substantial effects. Furthermore, the extent of sustained mHealth usage reported varies considerably across different studies. Therefore, it is necessary to systematically review the controlled trials of mHealth technology in solid organ transplant recipients, evaluate the methodological quality of each study, and synthesize data from high-quality, homogenous intervention studies, so as to clarify the effectiveness of mHealth technology in the follow-up management of organ transplantation and to determine the actual acceptance of mHealth technology among transplant recipients. The findings of this review will offer valuable insights and recommendations for the future development and update of mobile health devices, which meet the requirements of health economics.

Condition being studied The World Health Organization (WHO) has defined mHealth as the "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and

other wireless devices." With the burgeoning prevalence of smart devices and mobile applications, mHealth technology has been progressively employed in the prevention and management of chronic diseases. Solid organ transplant recipients necessitate regular follow-up, long-term administration of immunosuppressants, and the cultivation of healthy dietary and exercise habits to improve graft function and survival. Therefore, long-term and effective post-transplant follow-up management are crucial for enhancing both the survival rates and quality of life of organ transplant recipients. To date, dozens of studies have investigated the application of mHealth interventions on one or multiple aspects of follow-up and management among post-transplant recipients. However, the findings of these studies are markedly inconsistent. Although several systematic reviews have examined the impact and effectiveness of information technology-based(IT-based) interventions on self-management in renal transplant recipients, there is a notable absence of systematic reviews specifically addressing the effectiveness of mHealth interventions in the follow-up management of organ transplant recipients. While IT-based interventions encompass a wide range of health intervention activities utilizing various IT tools, mHealth interventions are more narrowly focused, primarily involving IT interventions based on mobile devices, related applications, and wearable devices. Therefore, this study aims to investigate the effectiveness of mHealth interventions in improving follow-up and management among solid organ transplant recipients.

METHODS

Search strategy We will search the following electronic databases for relevant published studies: PubMed, Web of Science, Scopus, Embase, CINAHL, and the Cochrane Library. The search period will be from database inception to June 2024. We will also identify grey literature by reviewing the reference lists of the included studies and any related reviews. The following three search terms will be used in this review: “mobile health”, “organ transplantation”, and “follow-up and management”, utilizing Boolean logic for combination. All possible spelling and synonyms will also be used for searching. The search strategies used a combination of Medical Subject Headings (MeSH) and Title/Abstract words adapted for each database. All searches will be carried out using the Preferred Reporting Items for Systematic Reviews and MetaAnalyses(PRISMA) guidance of Participants, Intervention, Comparator and Outcome method.

Participant or population This systematic review examines two primary populations: recipients after solid organ transplantation and/or their caregivers who utilize mHealth tools for managing recipients’ health outcomes. Caregivers include both professional caregivers (e.g., nurses and nursing assistants) and non-professional caregivers (e.g., family members and nannies). Solid organ transplantation encompasses lung, kidney, liver, heart, pancreas, small intestine, and combined organ transplants. Studies that report results from mixed samples (e.g., including both recipients and transplant candidates/organ donors) will be excluded, unless the results are independently reported for each group.

Intervention Participants in the intervention group should have received a mHealth intervention for one or multiple aspects of post-transplant follow-up care and management, including outpatient visits, home-based self-management, medication adherence, self-monitoring, exercise regulation, and dietary management. mHealth interventions are administered through a variety of mobile devices, such as mobile phones, smartphones, mobile applications, personal digital assistants, tablets, wearable activity monitors, or other wireless devices. Studies that only use mobile devices as a tool for sending text messages or video conferencing will be excluded, as these fundamental information technologies are already extensively and routinely used.

Comparator This systematic review will examine mHealth interventions in comparison to usual care. Usual care can be delivered routine follow-up management without mHealth technology or just use mobile device to receive SMS or group messages. Studies without control/comparator group will be excluded.

Study designs to be included All available controlled trials will be retrieved, encompassing both randomized controlled trials (RCTs) and non-randomized studies of interventions (NRSIs). The NRSIs include non-randomized controlled trials, cohort studies, and pre-post studies. Mixed-method studies will also be incorporated to ensure the comprehensive inclusion of pertinent quantitative data; for these studies, solely the quantitative results will be extracted. Exclusively qualitative research will be excluded.

Eligibility criteria Dissertations or conference papers that satisfy the inclusion criteria and have the full text accessible will be incorporated into the study. Pilot and feasibility trials will be included if they meet these inclusion criteria. Research that is

incomplete or lacks available full text will be excluded. Editorials, reviews, protocol, letters to the editor, commentary, and books will be excluded. Duplicate publications will be excluded. Studies published in English or Chinese.

Information sources Published studies will be sought in six electronic databases: PubMed, Web of Science, Scopus, Embase, CINAHL, and the Cochrane Library. The search period will be from database inception to June 2024. To ensure comprehensive coverage of potential references that may not be captured through electronic database searches, additional studies will be identified through hand-searching and by reviewing the reference lists of relevant papers. For studies whose abstracts meet the inclusion criteria but are not available for full text, we will contact the first or corresponding author to obtain the full text.

Main outcome(s) The main outcome of this systematic review encompasses a variety of health care outcomes, including self-management/self-care ability, physical activity, medication safety, nutritional status, quality of life, medical regimen adherence, incidence of complications (e.g., infections, rejection, and drug-related complications), re-hospitalization, emergency department visits, all-cause mortality. All forms and units of measurement will be accepted, encompassing both objective and subjective metrics, as well as data produced by mobile health devices. These measurements will facilitate the assessment of the impact and effectiveness of mHealth interventions in the follow-up and management of solid organ transplant recipients.

Additional outcome(s) Secondary outcome measures in this systematic review encompasses recipients' satisfaction with mobile health devices, their adoption and utilization rates, and their willingness to continue usage. These measurements can reflect the satisfaction and acceptance of mobile health devices among solid organ transplant recipients.

Data management The records retrieved from each database, as well as those manually retrieved, will initially be imported into EndNote 20.0.1 software (Clarivate Analytics, USA) for automatic and manual duplication checks. A team of three reviewers will evaluate the remaining studies. Two reviewers will independently screen the titles, abstracts, and full texts, with a third reviewer available to resolve any disagreements. The selection process for the studies will be meticulously documented in the PRISMA flow diagram. The selected studies will be cataloged in a Microsoft Excel spreadsheet (Washington, USA) and subsequently included for data extraction and analysis. A standardized data extraction form will be developed to offer structured guidance for the reviewers. To ensure comprehensive and unbiased data extraction, two reviewers will extract the data independently. A third reviewer will be brought in to resolve any disagreement. Interrater reliability will be assessed to ensure consistency. Corresponding authors will be contacted for further information as needed. The characteristics of excluded reviews and reasons for exclusion will be listed in a table.

Quality assessment / Risk of bias analysis Studies that meet the eligibility criteria for this review have either an RCT or NRSI design. Two reviewers will independently assess the risk of bias in selected studies using one of the following instruments based on the study design. For RCTs, the version 2 of the Cochrane Risk-of-Bias Tool for Randomized Trials (ROB 2) will be employed, which examines five domains of bias: (1) bias arising from the randomization process, (2) bias due to deviations from the intended intervention, (3) bias due to missing outcome data, (4) bias in measurement of the outcome, and (5) bias in selection of the reported result. For NRSIs, the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool recommended by Cochrane will be used, which evaluate seven bias domains: (1) bias due to confounding, (2) bias in selection of participants into the study, (3) bias in classification of interventions, (4) bias due to deviations from intended interventions, (5) bias due to missing data, (6) bias in measurement of the outcome, and (7) bias in selection of reported results. Thereafter, the over all bias judgment will be evaluated according to domain-level judgments. A third reviewer will be consulted for opinion in case of disagreement. Corresponding authors will be contacted for further information as needed.

Strategy of data synthesis A narrative synthesis of the extracted data will be conducted, and, where the characteristics of the eligible studies allow, a meta-analysis will also be performed. It will be reported in accordance with the PRISMA guidelines.

We will begin with a narrative synthesis that delineates the following elements: the category of mobile devices and applications employed in the studies, the description of the mHealth intervention, the specific aspects of post-transplant follow-up management addressed by mHealth interventions, the characteristics of the

sample population, and the levels of adherence to and acceptance of mHealth technology.

For primary and secondary outcome indicators, a meta-analysis will be conducted using RevMan 5.4 software if the number of original studies retrieved is sufficient and the study designs are homogeneous, otherwise, a narrative review will be performed. We will synthesize data by carrying out measurement of effects for the outcomes of the included studies. For dichotomous variables, relative risk (RR) and 95% confidence intervals (CI) will be extracted as effect sizes. For continuous variables, mean differences/standardized mean difference and standard deviations (SD) will be extracted. We will assess heterogeneity between studies using both $\chi 2$ and I2 where appropriate and use sensitivity analyses to determine the potential sources of heterogeneity. If I2 >50, this indicates substantial heterogeneity among the original studies, warranting the selection of a random effects model. Conversely, if the I2 ≤ 50, it signifies low heterogeneity, and a fixed effects model will be selected. Risk ratios for dichotomous variables and standardized mean differences for continuous variables will be calculated to provide summaries of the intervention effects. If the meta-analysis includes ≥10 studies, publication bias will be assessed by funnel plots and Eggers test will be used to determine the asymmetry of funnel plots. If the number of studies meeting the eligibility criteria is limited or there exists substantial heterogeneity among them, conducting a meta-analysis may not be appropriate. In such cases, a narrative synthesis will be employed.

Subgroup analysis Subgroup analysis will be performed, when possible, for diverse populations (e.g., recipients or caregivers) and varied assessment periods (e.g., < 1 year post-intervention or ≥ 1 year post-intervention).

Sensitivity analysis Sensitivity analysis will be performed, when possible, stratified by study design, including RCTs and NRSIs.

Language restriction Studies published in English or Chinese.

Country(ies) involved All authors contributing to this study are based in China, and their respective affiliations are also located within China.

Other relevant information This systematic review will use previously published studies and accordingly requires no ethical approval.

Keywords organ transplantation; mobile health; mHealth; follow-up; self-management; self-care.

Dissemination plans The findings of this systematic review will be submitted for publication in a peer-reviewed journal and may also be presented if accepted at a suitable medical conference.

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