

Development of a protocol for conducting a randomized control trial on effects of artificial intelligence on nutritional status of children post cardiac surgery

Maryam Zahid, Ume Sughra

Abstract

Objectives: To assess the effect of diet-related mobile application based on artificial intelligence on the nutritional status of children post-cardiac surgery, and to compare their diet-related problems with their counterparts having the usual diet.

Method: The two-arm double-blind randomised controlled trial will be conducted at a tertiary care hospital in Rawalpindi, Pakistan, over an expected duration of 6 months from March to August 2021. Intervention group A will be given a diet-related mobile application based on artificial intelligence, while usual-care group B will be handed a pamphlet with instructions related to post-operative diet on discharge.

Results: The findings will improve perception about the influence of artificial intelligence on nutritional status of children post-cardiac surgery. If proven to be effective, this mobile application can be used in other hospitals.

Conclusion: The study protocol will give an indication that whether diet-related mobile application can contribute to improving the nutritional status of children post-cardiac surgery. As the pandemic has forced people to minimise hospital visits, this is the right time to evaluate the utility of such an application.

Keywords: Artificial intelligence, Diet-related mobile application, Nutritional status, Children post-cardiac surgery, Randomised controlled trial.

Study was registered on clinicaltrials.gov with trial identity number NCT04782635.

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Introduction

Malnutrition is found in 15-50% children, and is the most common problem in paediatric patients having congenital heart diseases (CHDs).¹ Even in the developed nations, underfeeding is common in critically ill children,² whereas in the developing countries, the incidence of malnourishment may be even higher.³

In Pakistan, 17.7% children suffer from wasting.⁴ In a study,⁵ 21% patients had in-hospital mortality. Mortality in normal-weight babies was 3.4%, but increased to 47% in underweight, and 49% in severely underweight patients.

When devoted nutrition support teams have focussed on energy and protein intake, it produced better postoperative outcomes in high-income countries.⁶ In Pakistan, there is shortage of workforce to provide such knowledge in hospitals, so a mobile application would be helpful in creating nutritional awareness.⁶

Health and fitness-based mobile applications have recently emerged in the smartphone market in large numbers.⁷ They play an important role in tracking the intake of foods and drinks, which may help individuals improve understanding of their dietary patterns.⁸ Despite

Al Shifa Trust Eye Hospital, School of Public Health, Rawalpindi, Pakistan.

Correspondence: Maryam Zahid. Email: maryamzahid343@gmail.com

being economically beneficial, dietetic counselling requires plenty of time.⁹ Mobile health applications have become accessible,¹⁰ and present opportunities to increase the reach of dietetic services to those who may be unable to reach dietary clinics.¹¹

The proposed clinical trial will assess the effectiveness of a diet-related mobile application based on artificial intelligence (AI) on the nutritional status of cardiac postoperative children, and to compare their diet-related problems with their counterparts having the usual diet and care.

Methods

The two-arm double blind randomised controlled trial (RCT) will be conducted at a tertiary care hospital in Rawalpindi, Pakistan, over an expected duration of 6 months from March to August 2021. The RCT was registered with the clinicaltrials.gov (NCT04782635), and the recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)¹² will be followed as shown in Table-1.

The patient's enrollment will take about 10-14 weeks at the rate of 7-8 patients per week. The intervention is expected to be given for at least 8 weeks per patient. A specific inclusion/exclusion criteria will be followed (Table-2).

Patients using usual care will be blinded from those using

Table-1: Schedule of enrollment, intervention and assessment of the enrolled patients according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013.

Timepoint**	Baseline 1 week	Allocation 1 week	Intervention 1-8 week	First follow-up 5 week	Second follow-up 8-9 week
Enrolment:					
Eligibility screen	X				
Informed consent	X				
Nutritional status assessment	X				
Training regarding mobile application and pamphlets	X				
Allocation		X			
Interventions:					
Diet related mobile application			X	X	X
Pamphlets			X		
Assessments:					
Weight	X			X	X
Calories and protein intake	X			X	X
Mobile application usefulness				X	X
Nutritional issues	X			X	X
Carbohydrates, fats, Mineral, vitamin intake	X			X	X

Table-2: Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
1. Children of age 2-12 years will be included in the study.	1. Patients with multiple congenital abnormalities will be excluded from study
2. Surgeries within first and second class of RACHS score are included in the study.	2. Patients whose RACHS score is not mentioned will be excluded.
3. Patients with the facility of smart phones and internet will be included in the study.	3. Rehospitalized patient will be excluded from the research.
4. Patients/caregivers who can read English language will be included in the study	
5. Discharged patients will be included in research.	

the application. The random allocation of enrolled patients into the two groups will be performed using permuted block randomisation, making sure 1:1 ratio in intervention group A and usual-care group B. Recruitment of the patients will be carried out using the chronologically numbered sealed envelopes.

The primary objective of the diet-related mobile application would be to improve or maintain the nutritional status of the children. Children/caregivers will be able to choose their goals and challenges, daily intake of calories, carbohydrates, proteins, fats, minerals and vitamins. Nutritional intake will be tracked and daily and monthly insight regarding nutrients intake will be provided to the user. Meal and supplement reminders will be given to the users as per their requirements. Recipes will be available and meals can be planned according to the food choices of the child.

On discharge from hospital, the guardian/caregivers of children in group A will be explained the intervention and written consent will be requested. The mobile application will be installed in their mobile phones and they will be given the basic knowledge regarding the working of the application. Personal information will be entered in the

mobile application, which will produce a diet plan for the child.

The child will then use the mobile application for 4 weeks after which, during the routine visit, the caregiver will be asked about the effectiveness of the application, and the nutritional status of the child will be checked. The patient will follow the diet plan provided in the mobile application and will visit the doctor for routine check-up after another 4 weeks. During the hospital visit, the patient will be asked about the effectiveness of the application, and nutritional status of the patient will be checked.

in group B, the children's weight, height, clinical signs will be noted on discharge. A pamphlet with dietary information will be given to the caregivers. During the routine hospital visit after 4 weeks, the nutritional status of the patient will be checked. The same procedure will be followed when the patient will visit doctor after another 4 weeks.

The sample-size will be calculated using results from a previous study¹³ in which wasting was reduced by the end of the study in 12% subjects in the intervention group, but there was no marked difference between the

intervention and control groups at the end of the study. The sample size is likely to be 88; 44(50%) in both groups, with 80% power, 5% significance level and predicted dropout 25%.

In terms of primary outcomes, weight changes in pounds (lbs), average caloric intake in kcal and average protein intake in gm will be observed / calculated in both the groups for 8 weeks.

Patients will be requested to provide input regarding the usefulness of mobile application on Likert scales. The language used in the application as well as the usage of application itself will be rated from 'easy' to 'difficult'; financial effectiveness of the app will be rated from 'yes' to 'very costly'; insight about calories and nutrients will be rated from 'useful' to 'difficult to understand'; the recipes provided in the application will be rated from 'being useful' to 'not useful'; meal and supplement reminders will be rated from 'being useful' to 'irritating'.

Patients will be inquired about any nutritional issues faced during that period, like episodes of vomiting, diarrhoea, loss of appetite and other nutrition-related problems.

Secondary outcome measures would include average carbohydrates and fats consumed in both groups which will be recorded in gm for 8 weeks, and average vitamins and minerals consumed which will be recorded in mg and µg for 8 weeks.

Results

Ethical and institutional permission is being pursued. The recruitment of the subjects is planned, and the data-collection process is expected to be completed by July 2021. Results will be analysed subsequently. The research work is anticipated to be published within three months post-analysis.

Discussion

Malnutrition is common in CHD patients. Mehta et al. defined malnutrition as the difference between the nutrients requirement and the intake, which results in a collective insufficiency of energy, protein and micronutrients that may adversely affect growth and development.¹⁴

According to Becker et al., assessment of nutritional status and examinations on the role of nutrition in patient's health management should include data over a period of time. The data should include anthropometrics, actual dietary intake and reason for malabsorption.¹⁵

Application-based mobile health interventions are a

predominantly favourable method of modifying nutrition behaviours and health outcomes related to nutrition due to increased universal smartphone penetration and the easiness of installing apps in the mobile devices.¹⁶

Conclusion

The use of mobile health (mHealth) technology in the dietetic field has not been studied comprehensively and there has not been any RCT planned in Pakistan involving the effect of diet-related mobile application on nutritional status of children after cardiac surgery. The study protocol will give an indication that whether a diet-related mobile application can improve the nutritional status of children post-surgery. As the pandemic has forced the people to minimise hospital visits, this is the right time to evaluate the usefulness of such an application.

Disclaimer: The text is based on an academic research.

Conflict of Interest: None.

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