ISRCTN23135945 https://doi.org/10.1186/ISRCTN23135945

Study of blood glucose control in patients with steroid-induced diabetes mellitus

Submission date
04/11/2024

Recruitment status
No longer recruiting

Registration date
05/11/2024

Overall study status
Completed

Last Edited
28/04/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Mobile healthcare (mHealthcare) has been widely used to manage diabetes in developed countries, but it's still new in China. This study explores how internet-based health management can help patients record their health data using mobile devices, while healthcare providers monitor this data using big data platforms.

Who can participate?
Patients with nephrotic syndrome (NS) complicated by steroid-induced diabetes mellitus (SDM) can participate. The experimental group includes 15 men and 13 women, with an average age of about 69 years. The control group includes 14 men and 14 women, with an average age of about 65 years.

What does the study involve?
The control group receives routine health management through group education sessions during hospitalization. This includes group discussions and large classroom lectures about preventing and treating SDM. Education is provided once a week, with each session lasting about 1 to 1.5 hours. They do not use mobile educational platforms.

The experimental group uses a mobile educational platform for individualized health management. A team of healthcare professionals provides one-on-one guidance on weight control, diet, exercise, blood glucose monitoring, and self-management skills. Online education materials, such as videos and images, are also available on the platform.

What are the possible benefits and risks of participating?
Participants may benefit from improved self-management skills and better control of their condition. However, there may be risks associated with the new approach, and the effectiveness of the mobile platform is still being studied.

Where is the study run from?
The study is conducted at Shanxi People’s Hospital in China.

When is the study starting and how long is it expected to run for?
January 2019 to June 2021

Who is funding the study?
The study is funded by the Shanxi Province "136" Medical Engineering Research Project.

Who is the main contact?
For more information, you can contact Zhimin Yang at Zhimin_yang9@126.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Zhimin Yang

ORCID ID
https://orcid.org/0009-0009-7549-3456

Contact details
No. 359 Heping North Road, Jiancaoping District
Taiyuan City
China
030000
+86 13834601227
Zhimin_yang9@126.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SXYHP1001

Study information

Scientific Title
Positive impact of mobile educational platforms on blood glucose control in patients with nephrotic syndrome (NS) and steroid-induced diabetes mellitus (SDM): a randomized controlled study

Study objectives

The central hypothesis of this study is that a mobile educational platforms significantly resulted in better glycemic control and treatment adherence in the patients with NS and SDM compared with standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/10/2021, The Ethics Committee of Shanxi Provincial People's Hospital (No. 359 Heping North Road, Jiancaoping District, Taiyuan City, 030000, China; +86 03154961105; qinzhicheng9@hotmail.com), ref: (2021) Provincial Medical Department Ethical Review No. (272)

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nephrotic syndrome and steroid-induced diabetes mellitus

Interventions
The control group received routine health management (group education), where nurses provided collective health education orally and through manuals during hospitalisation, including group education and large classroom-based education. In the group education, patients in the control group were divided into two groups for separate instruction. Common issues among multiple patients were addressed through communication and guidance, with each educational session lasting around 1 h. Large classroom-based education was conducted in the form of lectures without grouping, where nurses explained knowledge related to the prevention and treatment of SDM to patients. Education was provided once a week, with each session lasting around 1.5 h. No access to mobile educational platforms was provided to this group, ensuring a clear comparison with the intervention group. This approach controlled for any influence that patient education might have on blood glucose management, allowing for isolating the effect of the mobile platform.

In contrast, a mobile educational platform was utilised to construct individualised health management (individual education) in the experimental group. First, a 6-member health management team was established on the mobile educational platform, consisting of 1 information liaison officer, 1 health manager, 2 responsible nurses and 2 doctors, all with work experience of >5 years. For offline education, nurses conducted one-on-one communication and guidance with the patients, with the education content including weight control, balanced diet, moderate exercise, blood glucose monitoring and guidance on self-management skills. Additionally, emphasis was placed on the participation of patients when setting health education goals. During the implementation of the programme, the goals for behaviour changes were refined, and feedback from patients was taken onboard to adjust the programme as needed. Regarding online education, relevant courseware, videos, images, etc. were created and subsequently uploaded to the mobile educational platform, with the content including routine

information about NS, risk factors leading to SDM, clinical manifestations, preventive measures, treatment and care. Moreover, remote education was conducted via mobile applications and online platforms to promote the self-management knowledge of patients with NS after using GCs and to enhance their self-management skills.

Intervention Type
Behavioural

Primary outcome(s)
1. Blood glucose levels (fasting glucose and postprandial blood glucose) measured using blood test at baseline and 3 months
2. Self-management efficacy measured using Diabetes Self-Management Attitude Scale, Diabetes Self-Management Behavior Scale and Diabetes Self-Efficacy Scale (DSES) scores, pre-intervention and 3 months after intervention

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/06/2021

Eligibility

Key inclusion criteria
Sure, here is the revised numbering format:

1. Patients with a confirmed diagnosis of NS and SDM for at least 3 months prior to enrollment.
1.1. NS was diagnosed based on nephrotic-range proteinuria (urinary protein excretion >3.5 g /day), hypoalbuminemia (serum albumin <3.0 g/dL), and clinical evidence of edema.
1.2. SDM was diagnosed using the American Diabetes Association criteria, requiring fasting plasma glucose ≥126 mg/dL, 2-hour plasma glucose ≥200 mg/dL during an oral glucose tolerance test, or haemoglobin A1c (HbA1c) levels ≥6.5%.
2. Aged >18 years.
3. Patients who were able to use smartphones or computers.
4. With outpatient follow-up for 3 months or above to ensure treatment adherence and stability.
5. Patients whose initial dose of GCs ≥40 mg/d (prednisone dose).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit

81 years

Sex
All

Total final enrolment
56

Key exclusion criteria
1. History of diabetes or impaired glucose tolerance before GC use
2. Severe infection, stress response and other factors caused by significantly elevated blood glucose

Date of first enrolment
01/04/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
China

Study participating centre
Shanxi Provincial People's Hospital
No. 359 Heping North Road, Jiancaoping District
Taiyuan City
China
030000

Sponsor information

Organisation
Shanxi Provincial People's Hospital

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and /or analysed during the current study will be available upon request from Dr Zhimin Yang, Zhimin_yang9@126.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/04/2025	28/04/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes