

# The role of clinical pharmacists' intervention on improving the adherence to treatment and clinical outcomes among hemodialysis patients

<b>Submission date</b> 23/03/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/07/2022	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hemodialysis is a procedure where a dialysis machine and a special filter called an artificial kidney, or a dialyzer, are used to clean your blood.

Following treatment recommendations (adherence) is challenging in hemodialysis (HD) patients, yet it has been found to be extremely crucial in obtaining positive clinical and health outcomes. This study aimed to evaluate the role of clinical pharmacists in enhancing HD patients' adherence to treatment recommendations and improving clinical outcomes.

### Who can participate?

Adult (over 18 years) hemodialysis patients who have been undergoing dialysis for more than three months

### What does the study involve?

Patients will receive a monthly educational session, for three months, that covers the disease and its management with recommendations for improving adherence and quality of life. An instructional booklet will be handed to participants in the intervention group as well.

### What are the possible benefits and risks of participating?

This study will be beneficial to participants in improving management outcomes. No minimal risk is expected.

### Where is the study run from?

Jordan University of Science and Technology

### When is the study starting and how long is it expected to run for?

March 2021 to November 2021

### Who is funding the study?

This work was supported by the Deanship of Scientific Research at Jordan University of Science and Technology (grant number 232/2021).

Who is the main contact?

Dr Osama Alshogran, oyalshogran@just.edu.jo

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Osama Alshogran

### ORCID ID

<https://orcid.org/0000-0002-2466-4763>

### Contact details

Faculty of Pharmacy/Jordan University of Science and Technology

Irbid

Jordan

22110

+962 798318927

oyalshogran@just.edu.jo

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Grant number 232/2021

## Study information

### Scientific Title

The role of clinical pharmacist in enhancing hemodialysis patients' adherence and clinical outcomes: a randomized-controlled study

### Study objectives

The intervention group, which received education from a clinical pharmacist, would be more committed to the recommendations, have fewer complications, and improved clinical outcomes, as compared to the control group (who received standard medical care provided by other health care providers).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 26/04/2021, Institutional review board (IRB) committee at Jordan University of Science and Technology (King Abdullah University 7th Floor - Wing D., Amman - Ramtha highway Irbid Jordan; +962 2 7200600 Ext. (45102); IRB@just.edu.jo), ref: 11/140/2021

## **Study design**

Randomized open-label clinical trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Adherence to treatment in dialysis patients

## **Interventions**

Using stratified sampling based on age and gender, eligible patients were randomly assigned to intervention or control groups.

The intervention group will receive an educational instructional session by a clinical pharmacist that covers recommendations about the disease and its complications, medication information and adherence, common adverse drug events and how to prevent them, the value of adherence to diet and fluid restrictions, the importance of regular follow-up with the medical team and undertaking required laboratory testing, and doing exercise.

The control will receive the usual care.

Follow up is for 3 months.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Overall adherence to treatment recommendations assessed using a previously validated ESRD-AQ tool. This was assessed at baseline and after three months of follow up

## **Key secondary outcome(s)**

1. Quality of life measured using KDQOLTM-36 at baseline and after three months of follow up
2. Disease awareness measured using interview with clinical pharmacist at baseline and after three months of follow up
3. Number of emergency or hospital admissions measured using patient records for three months of follow up
4. Biochemical measurements included serum levels of sodium, potassium, urea, creatinine, albumin, hemoglobin level, calcium, phosphorus, and PTH which were obtained from patients' medical records at baseline and after three months of follow up

## **Completion date**

30/11/2021

## **Eligibility**

### **Key inclusion criteria**

1. At least 18 years old
2. Been on continuous HD for at least three months
3. Stable medical condition

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

114

**Key exclusion criteria**

1. Mental disease
2. Malignancies
3. Acute illness
4. Terminally ill
5. Under irregular dialysis

**Date of first enrolment**

01/05/2021

**Date of final enrolment**

01/09/2021

**Locations****Countries of recruitment**

Jordan

**Study participating centre**

**King Abdullah University Hospital**

Irbid

Jordan

22110

**Study participating centre**

**Al-Rashid Hospital**

Amman

Jordan

11937

**Study participating centre**  
**Al-Essra Hospital**  
Amman  
Jordan  
11941

## Sponsor information

**Organisation**  
Jordan University of Science and Technology

**ROR**  
<https://ror.org/03y8mtb59>

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
Deanship of Research, Jordan University of Science and Technology

**Alternative Name(s)**

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Universities (academic only)

**Location**  
Jordan

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analyzed during the current study are/will be available upon reasonable request from authors  
oyalshogran@just.edu.jo

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		12/07/2022	14/07/2022	Yes	No