Trial record **2 of 15** for: FES cycling | Recruiting, Not yet recruiting Studies

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Motor-assisted Cycling and FES Cycling for Postprandial Glucose in Diabetic Patients With ADL Disability

ClinicalTrials.gov Identifier: NCT03994289

Recruitment Status : Recruiting
First Posted : June 21, 2019
Last Update Posted : June 24, 2019

See **Contacts and Locations**

Sponsor:
Arizona State University

Information provided by (Responsible Party):
Chong Lee, Arizona State University

Study Details | **Tabular View** | **No Results Posted** | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

Exercise has been the cornerstone of diabetes management. However, many diabetic patients have ADL disabilities and experience substantial difficulty in performing usual exercises, such as brisk walking and upright **cycling**. There is an urgent need to provide alternative exercise modalities for diabetic patients with ADL disabilities. In this study, investigators will investigate the effects on the glucose of three exercise modalities, including motor-assisted **cycling** (i.e., **cycling** on a motor-driven bike) and functional electrical stimulation (**FES**) **cycling**, during which the investigators will use electrical current to facilitate **cycling** movements.

Condition or disease	Intervention/treatment	Phase
Type2 Diabetes Disability Physical	Behavioral: Motor-assisted **cycling** Behavioral: **FES cycling**	Not Applicable

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	12 participants
Allocation:	Randomized
Intervention Model:	Crossover Assignment
Masking:	Triple (Participant, Care Provider, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	Effects of Motor-assisted **Cycling** and Functional Electrical Stimulation **Cycling** on Postprandial Glucose in Type 2 Diabetic Patients With Activities of Daily Living Disability
Actual Study Start Date :	February 20, 2019
Estimated Primary Completion Date :	October 20, 2019
Estimated Study Completion Date :	October 20, 2019

Resource links provided by the National Library of Medicine NIH NLM

Genetics Home Reference related topics: Type 2 diabetes

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
No Intervention: Control Participants remain seated for 2 hours after the intake of a standardized breakfast.	
Experimental: Motor-assisted **cycling** Participants will perform 3 bouts of motor-assisted **cycling**, each bout lasting 10 minutes, after the intake of a standardized breakfast.	Behavioral: Motor-assisted **cycling** Participants will perform the motor-assisted **cycling** exercise using a physical therapy bike (RECK; Betzenweiler, Germany). Participants will perform 3×10-min bouts of motor-assisted **cycling**. The motor-assisted **cycling** exercise is aimed to elicit a heart rate of 65-70% of HRmax, which is moderate intensity exercise based on the ACSM guidelines. Before each bout, participants will perform 1-2 minutes of motor-assisted **cycling** at 5-10 rpm as a warm-up.
Experimental: **FES cycling** Participants will perform 3 bouts of **FES cycling**, each	Behavioral: **FES cycling** The testing procedures will be identical to that in the motor-assisted **cycling** visit except for the exercise type.

bout lasting 10 minutes, after the intake of a standardized breakfast.	. The **FES cycling** will be performed on the motor-assisted bike using the wearable **FES** equipment. The purpose of motor-assisted **cycling** is to provide constant cadence. The Bioness L300 Plus system (Bioness, Valencia, CA) will be worn on the upper and lower legs to stimulates the quadriceps and dorsiflexors muscles during the motor-driven **cycling** exercise. An embedded gyroscope of the cuff can detect the motion of the lower leg so that the electrical stimulations will be generated at appropriate timing to activate leg muscles during the **cycling** exercise.

Outcome Measures

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Primary Outcome Measures :

1. Postprandial glucose AUC [Time Frame: The glucose will be measured using CGM during the 2-hour postprandial period.]

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	60 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age above 60 years.
- Physician-diagnosed type 2 diabetes.
- ADL disability (self-reported).

Exclusion Criteria:

- Fasting glucose ≥ 250 mg/dL.
- Symptomatic hypoglycemic events in the past three months.
- Insulin injection or infusion
- Systolic blood pressure ≥ 160 mmHg OR Diastolic blood pressure ≥ 100 mmHg
- Diagnosis of NYHA class I-IV heart failure
- Myocardial infarction in the past 6 months
- Recent or current angina, shortness of breath, or other symptoms suggestive of heart failure
- Diagnosed Cancer
- Unable to consent due to impaired cognitive function
- Bone fracture, joint dislocation, or joint stiffness
- Local skin disorders at the FES cuff area or CGM sensor area
- Implantable electronic or metallic devices, such as cardioverter defibrillator and pacemaker

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03994289***

Contacts

Contact: Tongyu Ma, M.S. 602566 ext 2501 tongyuma@asu.edu

Locations

United States, Arizona

Brookdale Senior Living Central Chandler **Recruiting**
Chandler, Arizona, United States, 85224
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Sponsors and Collaborators

Arizona State University

More Information

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Responsible Party: Chong Lee, Associate Professor, Arizona State University
ClinicalTrials.gov Identifier: NCT03994289 History of Changes
Other Study ID Numbers: STUDY00008262
First Posted: June 21, 2019 Key Record Dates
Last Update Posted: June 24, 2019
Last Verified: June 2019

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Chong Lee, Arizona State University:

exercise

FES