Study Protocol

Home-based Resistance Training to Patients With Type 2 Diabetes

NCT04755660

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Study Protocol

Purpose: The purpose of the study is to explore the efficacy of a theory-based resistance exercise intervention and a resistance band exercise training on the level of physical activity, muscle strength body composition, exercise self-efficacy, and exercise adherence in adults with type 2 diabetes.

Methods: The study is a three-arm parallel randomized clinical trial. Participants were recruited from metabolism outpatient clinics. A total of 90 adults with type 2 diabetes were recruited and randomly assigned to the theory-based resistance exercise group, the resistance band exercise training group, or the control group. All groups underwent a 12-week intervention program. The theory-based resistance exercise group received a 12-week motivational interviewing and self-efficacy based resistance exercise training. The resistance band exercise group received a 12-week resistance band exercise training. All participants were introduced to exercise three times a week and at least thirty minutes a day on alterative day. The control group received a brief exercise instruction. Data were collected at the pretest, 6th week, and 12th week on handgrip strength, 6 meters walking speed (6 MWS), 30 seconds sit to stand (30’ STS), self-reported physical activity, and exercise self-efficacy. The participants were asked to keep daily exercise dialog as well.

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人體試驗委員會
同意人體研究證明書

計畫名稱：比較行為介入與居家阻力運動訓練對改善第二型糖尿病病人身體活動量與肌力之成效：隨機分派臨床研究
計畫書編號/本會審查編號：20201202R
計畫書版本/日期：Version 3，2021-03-03
計畫總主持人：林婷茹
計畫主持人所屬機構：新光醫療財團法人新光吳火獅紀念醫院台北護理健康大學
受試者同意書版本/日期：Version 2，2020-12-28
通過會期：No.3/2021-3-11
核准效期：2021-01-18 至 2022-01-17
計畫追蹤頻率：每 12 個月一次。
期中報告繳交期限：2022-01-17(建議於前 6 週完成繳交以利期限前審畢)
結案報告繳交期限：2022-03-17(核准效期迄日後 2 個月內繳交)
其他：個案檢查資料登錄查核表 Version 2，2020-12-28、運動日誌 Version 2，2020-12-28、個案招募篩檢表 Version 1，2020-11-30、個案基本資料表 Version 1，2020-11-30、運動自我效能量表 Version 1，2020-11-30、老人身體活動量表 Version 1，2020-11-30、招募海報 Version 1，2020-11-30

Institutional Review Board
Approval of Human Study

Protocol Title：Comparing the Efficacy of a Behavioral Intervention and a Home-based Resistance Training of Physical Activity and Muscle Strength in Patients with Type 2 Diabetes: A Randomized Clinical Trial
Protocol No./IRB No.：20201202R
Protocol Version/Date：Version 3，2021-03-03
Chief Principal Investigator：Ting-Ru Lin
Informed Consent Form/Date：Version 2，2020-12-28
Board Meeting/Approval Date：No.3/2021-3-11
Study Approval Expiry Date：2022-01-17
Mid-Term Report Submission Deadline：2022-01-17
Final Report Submission Deadline：2022-03-17
Others：個案檢查資料登錄查核表 Version 2，2020-12-28、運動日誌 Version 2，2020-12-28、個案招募篩檢表 Version 1，2020-11-30、個案基本資料表 Version 1，2020-11-30、運動自我效能量表 Version 1，2020-11-30、老人身體活動量表 Version 1，2020-11-30、招募海報 Version 1，2020-11-30
The above study is approved by the Institutional Review Board on 2021-02-18.

1. 若您須展延核准效期，應於效期前提出並獲准展延。請您最遲於前 6 週繳交期中報告及變更案(展延)。
2. 若您未能提早送交報告而於到期前尚未得到 IRB 展延許可、期中報告核備(包含已送件審查中)，請於效期日後暫停執行(不可收新案)，直到獲得 IRB 同意核備期中報告、核准繼續執行通知。例如：直至 2015-12-31 您尚未獲 IRB 正式許可展延，請於 2016-1-1 起先暫停執行計畫，直到取得期中報告核備與展延許可。
3. 計畫主持人對受試者任何保具有危險而且未能預期之問題，例如：對藥物、放射性元素或對醫療器材產生嚴重或非預期不良反應等，需立即向本委員會提出書面報告。

本院人體試驗委員會之組織與執行皆符合 ICH-GCP
The Institutional Review Board of Shin Kong Wu Ho-Su Memorial Hospital performs its functions according to written operating procedures and complies with GCP and with the applicable regulatory requirements.

Yours sincerely,
Gong-Jhe Wu, M.D., Ph.D.
IRB Chairman
Shin Kong Wu Ho-Su Memorial Hospital
Taiwan R.O.C.

審查編號：20201202R　　B 版
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