Informed Consent Form

A pilot study to assess the feasibility and adherence of a sleep improvement intervention for weight loss and its maintenance in sleep impaired obese adults

Dr. Teresa Arora

This consent form, a copy of which will been given to you, is part of the process of informed consent required by the Zayed University Ethics Committee. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Please take the time to read this form carefully and to understand any accompanying information.

Invitation to Participate

I am conducting a research study to assess the feasibility and adherence to a lifestyle intervention for weight loss and weight loss maintenance. My name is Dr. Teresa Arora and I am an Assistant Professor at Zayed University, College of Natural and Health Sciences. I would like to invite you to participate in this research project.

Research Purpose

The purpose of the research project is to investigate the feasibility and adherence to a lifestyle intervention for weight loss and weight loss maintenance. The results of the research will be used to inform the development of a larger trial in the future.

Research Method

If you decide to participate, you will be asked to complete three sleep questionnaires to assess the possibility of an undiagnosed sleep disorder (obstructive sleep apnea). You will also be asked some questions about your medical history as well as some demographic questions such as age and gender. The researcher will measure your height, weight, blood pressure, metabolic rate, as well as hip, waist and neck circumference and you will be asked to complete several questionnaires relating to sleep, mood, quality of life, and diet. You will then be provided with a wearable wrist monitor, called an actigraph, which you will be asked to wear for one week. This device is similar to a wearable activity monitor and is used to estimate sleep. Should you meet all of the study criteria then you will be invited to continue in the study and will then be randomized (have an equal chance) to one of two lifestyle conditions to help you to lose weight. Every week, for six weeks (60-minute sessions), you will be supported, and receive guidance from a behaviour change expert. The sessions will focus on improving diet/nutrition, physical activity and sleep (depending on which group you are randomized to). After you have undertaken these sessions, you will be provided with Cambridge Weight Plan products, as well as 600-800 calorie meal recipes, to support weight loss for 12 weeks. During these 12 weeks, you will wear the actigraph to estimate your sleep and you will receive a weekly phone call from our research team to check your progress. You will also need to attend the clinic across the 12 weeks to discuss any problems that you may be facing and to check your progress. During these visits we will also measure your weight, blood pressure, metabolic rate, as well as hip, waist and neck circumference and you will be asked to complete questionnaires relating to sleep, mood, quality of life, and diet. At the end of this 12-week period, you will receive further nutritional advice to support about continuing with a healthy lifestyle to maintain weight loss. You will then come back to the clinic once a month so that we can measure your weight, blood pressure, metabolic rate, as well as hip, waist and neck circumference. You will also be asked to questionnaires relating to sleep, mood, quality of life, and diet.

Your Professional Opinion

The research results will be used to inform a larger future trial to support individuals to lose weight and maintain weight loss.

Confidentiality - Anonymity - Security

If you decide to participate, your identity as a participant in this study, and any other personal information gathered about you during the study will be kept strictly confidential and will never be made public. All data containing personal information from which you could be identified will be stored in a filing cabinet in my office during the study. Electronic data will be password protected. When the study is completed, I will destroy all data containing personal information. The published results of the study will contain only statistical or group data from which no individual participant can be identified.

Okay To Say No

You are being asked to make a voluntary decision whether or not to participate in this study. Please read and think about the information given above. If there is any part of the information you do not understand, please ask me to explain it. If you would like to consult with someone not associated with this study that will be all right, too. If you decide not to participate, or if you later decide to discontinue your participation, your decision will not affect your present or future relations with Zayed University or Imperial College London Diabetes Center. Upon request, a copy of the information, data, and results will be made available to you. You will always be free to discontinue participation at any time, and all data collected up to that time as a result of your partial participation will be destroyed without being used in the study. If you decide to participate, please provide your signature as indicated below. Your signature below indicates that you have read, considered, and understood the information provided above, and that you have decided to participate.

What Your Signature Means

Your signature on this Consent Form indicates that you have understood and that you are satisfied the information regarding participation in this research project and that you agree to participate. In no way does this waive you legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time. Your continued participation should be informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

Signature of Participant Date

Print Name:

Signature of Investigator Date

Contact Information

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If you have any questions concerning your participation in this project you may also contact
Dr. Mercedes Sheen, Chair of the ZU Research Ethics Committee
Zayed University, (+971 4 402 1824).

A copy of this consent form has been given to you for your records and reference.