

**Title: Evaluation of the teaching utility of a computerized diabetes simulation program**

**Background Information:** Your doctor / diabetes clinic is interested in using a novel computer program for education about diabetes. This program can simulate many of the different types of diabetes problems that people with diabetes can encounter, and allows users to try and solve them in different ways. However, although many people have used this simulation program for diabetes teaching and self-learning, its actual role in supporting the education of people with diabetes mellitus remains to be formally confirmed.

The current study aims to address this issue by conducting a 'randomised controlled trial' using the simulation program in diabetes lessons. One half of a group of people with diabetes will be randomly assigned to receive lessons with the diabetes simulator first, while the other half of the group will receive standard (or conventional) lessons about diabetes first. Those people that are randomly assigned to receive conventional lessons first, will subsequently be offered a set of lessons with the diabetes simulator, a month after the end of their conventional lessons. In this way, everyone who participates in this study should have a chance to receive lessons involving the novel diabetes simulator.

**Understanding of Participant:** I have been asked to take part in a study that evaluates the usefulness of a novel diabetes simulation program. To this end I will take part in a study consisting of six conventional lessons (with graphs, transparencies & oral presentations) and / or six lessons with a computerized diabetes simulator. I understand that the exact dates and times of the lessons will be arranged directly with my fellow participants & I, and that the sequence of my participation in the study (conventional / standard lessons first or simulation lessons first) will be randomly determined.

**My involvement will be limited to:**

- 1) I will complete a logbook with my home blood glucose values the week before the start of the lessons, and the week following the end of the lessons. I will also record any symptoms of hypoglycemia ('hypos') and the blood glucose value at that time.
- 2) I will have my glycosylated hemoglobin (HbA<sub>1c</sub>) level checked before the start of the lessons, and one month after the end of the lessons.
- 3) I will complete some questionnaires regarding my subjective feeling of well being, and the impact of the lessons on my perceived well being.
- 4) I will participate actively in the lessons.

I understand that there is no risk to my health from this study, and that no form of medical therapy will be introduced for study. *I note that the diabetes simulator cannot be used to tailor my individual therapy. I appreciate that the only aim of the simulation program is to help me understand the mechanisms that govern blood glucose control in the human body, so I may understand better the processes involved in balancing insulin and diet in diabetes therapy. However it is quite clear to me that any insulin dosage adjustments made during the course of the study will be absolutely independent of the diabetes simulator, and will be discussed fully with my diabetologist / diabetes educator, as per normal.*

I agree not to make use of the computerized diabetes simulation program myself during the period of the study to avoid unnecessarily influencing the results.

The study has been explained to me by \_\_\_\_\_  
and I have had all my questions answered.

continued overleaf ....

**Participant's name:** (please print) \_\_\_\_\_

Participant's signature: \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / 2001

**Principal Investigator:** (Dr. \_\_\_\_\_ \*) (\* Please print name)

Principal Investigator's signature \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / 2001

**Witness:** Diabetes Educator / Nurse ( \_\_\_\_\_ \*)

Diabetes Educator / Nurse's signature \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / 2001

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Centre Name: Department of Diabetes / Endocrinology \*\* (\*\* Please delete as applicable)

Hospital / Clinic: \_\_\_\_\_

Clinic Address: \_\_\_\_\_

Centre ID Number (if applicable): \_\_\_\_\_

Local Ethical Committee Reference Number (if applicable): \_\_\_\_\_

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