FINAL REPORT

The validation of electronic diary (PRO-Diary) compared to validated paper questionnaires in normal individuals

Prepared for CamNtech Ltd by the University of Surrey

8th February 2011

Project supervisors: Dr Shelagh Hampton and Dr Benita Middleton
Faculty of Health and Medical Sciences
University of Surrey
Guildford
GU2 7XH

Summary

A 2 way randomised cross-over study was carried out in 50 individuals to compare paper versus electronic questionnaires. Three questionnaires were trialled: - food, sleep and mood /alertness. The food visual analogue scales (VAS) were completed prior to and after consuming a cereal bar. The sleep and mood/alertness questionnaire were completed for 7 days with the mood/alertness questionnaire being completed three times a day.

Food VAS data showed similar results after all observations except for how full do you feel with the last two time-points falling well below baseline values in the paper questionnaire responses. It could be suggested that the PRO-Diary gives a more realistic response.

The sleep diary showed no significant differences in all observations except light on time however as the subjects get up time was not significantly different this is probably due to time of the year when recording the data as some individuals did not need to switch on artificial lights as natural daylight was sufficient so any time was entered..

The mood and alertness questionnaires all results show no significant difference except for two observations at 2100h where KSS and how calm would you rate your mood observations were different. This may indicate boredom associated with the study as this was the last time-point in the day or could be related to a drop in concentration for memorising answers already recorded.

Introduction

Many studies require regular recording of observations such as food visual analogue scales, mood /alertness and sleep states or answers to specific questions at predetermined times. At the current time much of this data is collected on paper relying on compliance from the participant to complete the tests at the prescribed times, particularly for field studies. This does not provide the researcher with an objective electronic record of the time the test was actually completed. Collection of data in this way relies on manual transcription to transfer the data into electronic format. This is extremely time consuming and may result in errors.

The present study investigates using the PRO-Diary compared with paper questionnaires with respect to food, mood/alertness and sleep observations. Prior to commencement of the study a favourable ethical opinion was obtain from the University Ethics Committee (EC/2010/55/FHMS).

Protocol

Fifty healthy participants were recruited from the postgraduate students or staff at the University of Surrey and from the general public. Recruitment was by word of mouth and e-mail. Participants were recruited following completion of a general questionnaire (Appendix 1). An information sheet was given to each participant regarding the study. Prior to commencement of the study participants were asked to sign an informed consent form. All participants' information was coded. All information and data is kept strictly confidential as required by the Data Protection Act (1998).

Participant criteria for inclusion in the study

1. Aged between 20-60 years.
2. Normal Healthy Individuals

3. Able and willing to sign inform consent

Participant criteria for exclusion from the study

4. Unable to give informed written consent

5. Have been diagnosed with a sleeping or eating disorder

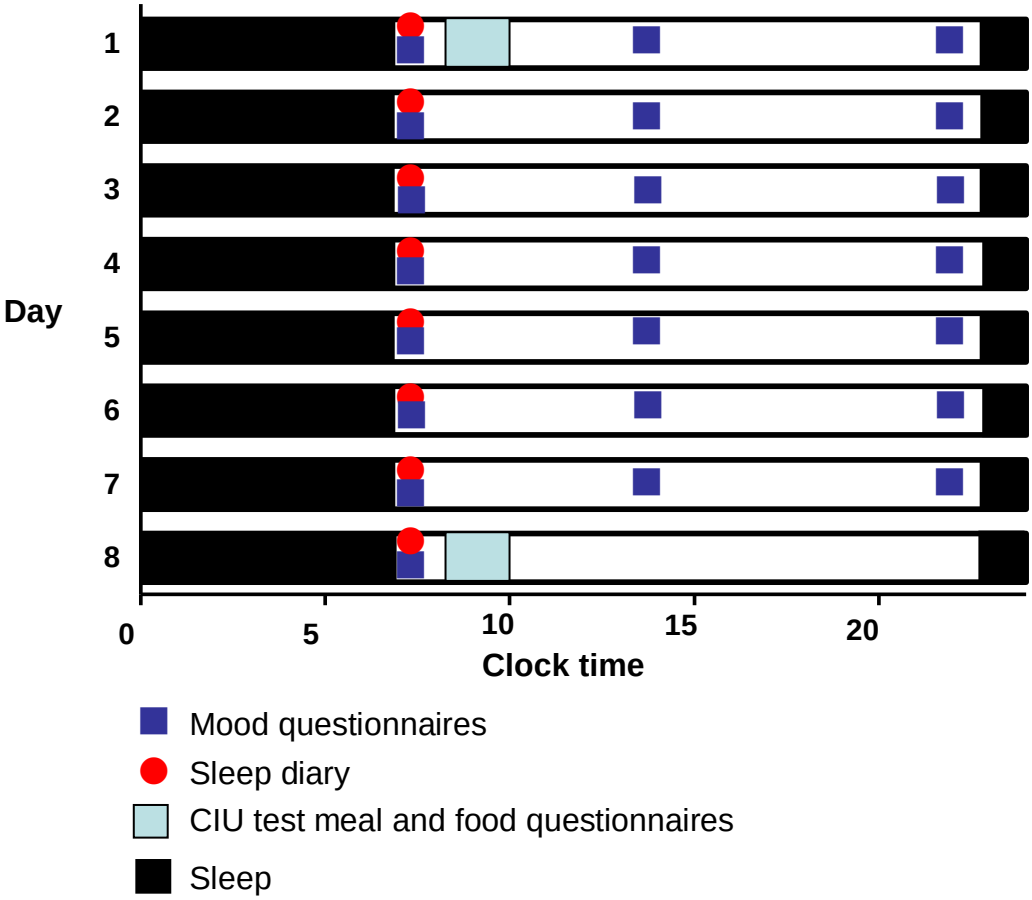
Study design (see Figure 1)

Each participant attended the Clinical Investigation Unit (CIU) on two occasions a minimum of seven days apart. Participants were allocated into Group A and B randomly. Group A were asked to complete the sleep diary and mood/alertness questions on paper each day after which they recorded the data on the electronic diary (PRO-Diary). Group B were asked to complete the sleep diary and mood /alertness questions using the electronic diary (PRO-Diary) first each day followed by the paper questionnaires.

Volunteers consumed a standardised evening meal prior to 20:00h on the evening prior to attending the CIU. The meal consisted of lasagne and yoghurt (460Kcals) which was the same on both occasions and was provided by the researchers. Nothing was eaten or drunk, apart from water, until arrival at the CIU. On the morning of the laboratory based study participants completed the first set of sleep diary (Appendix 2) and mood/alertness questionnaires (Appendix 3) after they received instructions regarding the study. On days 1 through to day 8 participants were asked to complete the sleep dairies in the early morning referring to the previous nights sleep on both paper forms and electronic. They also completed mood and alertness questionnaires in the early morning (09:00h), at lunchtime (14:00h) and in the evening (21:00h) prior to going to bed on paper and on the electronic diary. The PRO-Diary was set to alarm at these times to remind participants to carry out the tests.

On arrival in a fasted state at the CIU (Day 1 and Day 8) participants were given the food VAS questionnaire (Appendix 4) to complete at time 0. The paper VAS questionnaires were individually produced so that the questions could be randomised to remove any order effect. These PRO-Diary questions were set to occur randomly. Group A completed the PRO-Diary on the first occasion and on their second visit the paper questionnaire. Group B completed the protocol in reverse. Each participant was given a cereal bar (88 Kcal) plus 200 ml water and asked to complete the food VAS scales at 15 min, 30 min, 45 min, 60 min, 75 min and 90 min after ingestion.

Figure 1 Study Protocol



The first group of participants (n=25) carried the PRO-Diary in their pockets or plastic wallets which also contained the paper questionnaires. The second group of participants (n=25) wore the PRO-Diary on their wrists.

Statistical methods

Food VAS and mood/alertness paper questionnaires were manually scored and entered into the spreadsheet. The sleep questionnaires were also entered manually. The PRO-Diary data was downloaded and transferred to Excel spreadsheet.

Statistical analysis was undertaken on the raw data and data produced from the calculated difference between digital and paper results. Two way repeated measures ANOVA (factors, time and treatment) was used to analysis all VAS data generated from the study. Any differences were located with a Tukey's post –hoc tests.

Statistical significance was taken as $p<0.05$. Data represents mean ± SEM unless otherwise stated.

Results

Fifty participants volunteered to take part in the study. One withdrew after only completing one leg of the food questionnaire. The mean age was 31±11.5 year (mean ±SD) ranging from 19-59 years with a mean BMI 22 ± 4.81 kg/m^2.

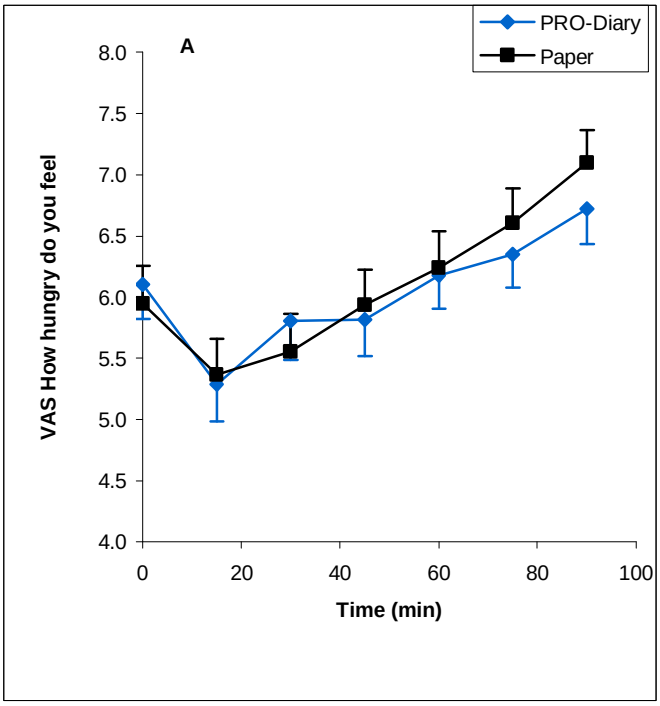
Analysis of questionnaires

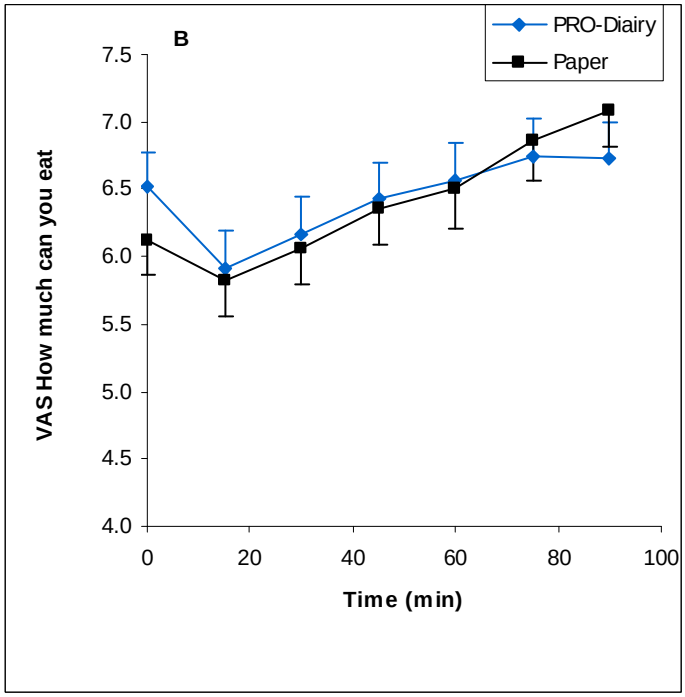
Analysis of Food Visual Analogue Scales

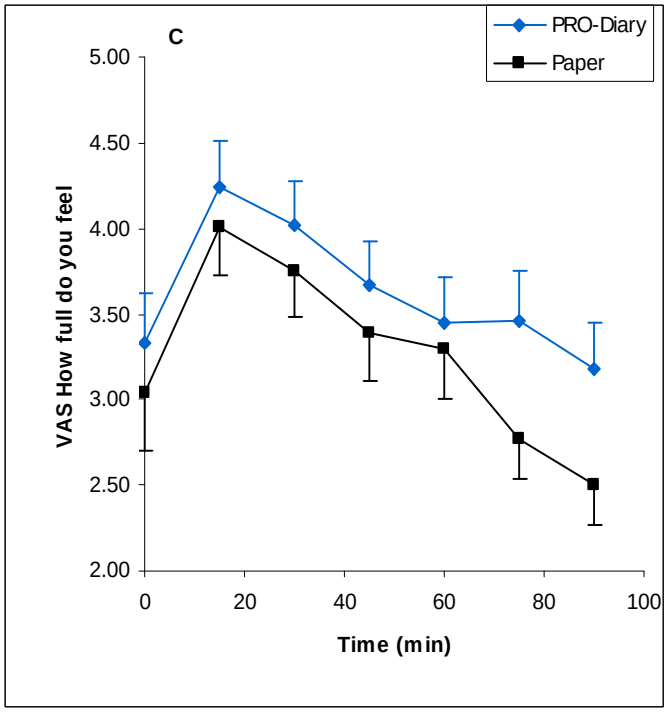
VAS data for the following criteria;- How hungry do you feel, How much can you eat, How full do you feel, How thirsty do you feel, Would you like something sweet, Would you like

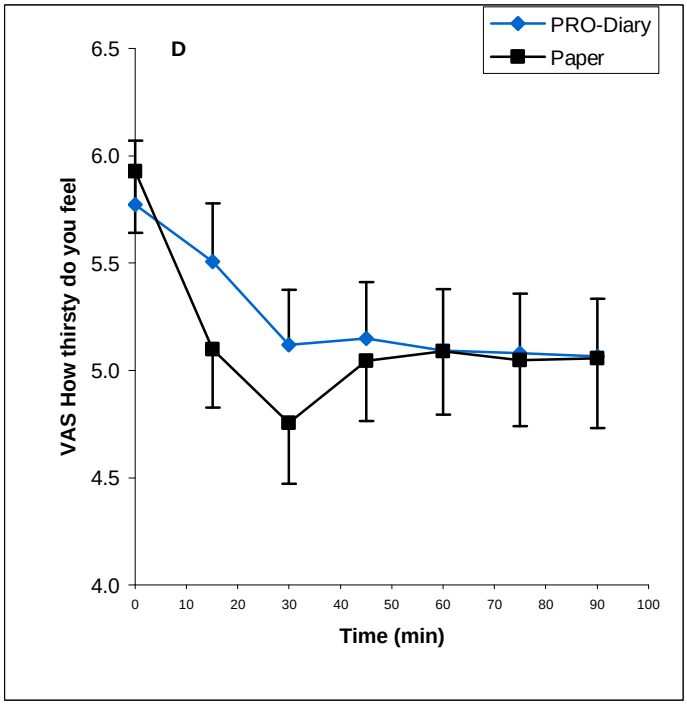
something savoury, Would you like something salty, Would you like to eat something fatty are represented in graphical form below. (Figure 2- A,B,C,D,E,F,G)

Two way RM-ANOVA showed a significant effect of time for all types of food VAS questionnaires. No significant differences were observed after carrying out RM- ANOVA between the PRO-Diary and the paper food VAS questionnaire except for how full the participant felt. Participants were significantly less hungry with they used the PRO-Diary than when they used paper ($p=0.04$). The difference between PRO-Diary and manual data was calculated to establish correlation by plotting the difference and including 95% confidence limits at each time point for the three major responses- how hungry do you feel, how much can you eat and how full do you feel.(Figure 3A,3B and 3C).


A
PRO-Diary
Paper
VAS How hungry do you feel
8.0
7.5
7.0
6.5
6.0
5.5
5.0
4.5
4.0
0
20
40
60
80
100
Time (min)


B
PRO-Diairy
Paper
VAS How much can you eat
7.5
7.0
6.5
6.0
5.5
5.0
4.5
4.0
0
20
40
60
80
100
Time (min)


C
PRO-Diary
Paper
VAS How full do you feel
5.00
4.50
4.00
3.50
3.00
2.50
2.00
0
20
40
60
80
100
Time (min)


D
PRO-Diary
Paper
VAS How thirsty do you feel
6.5
6.0
5.5
5.0
4.5
4.0
0
10
20
30
40
50
60
70
80
90
100
Time (min)

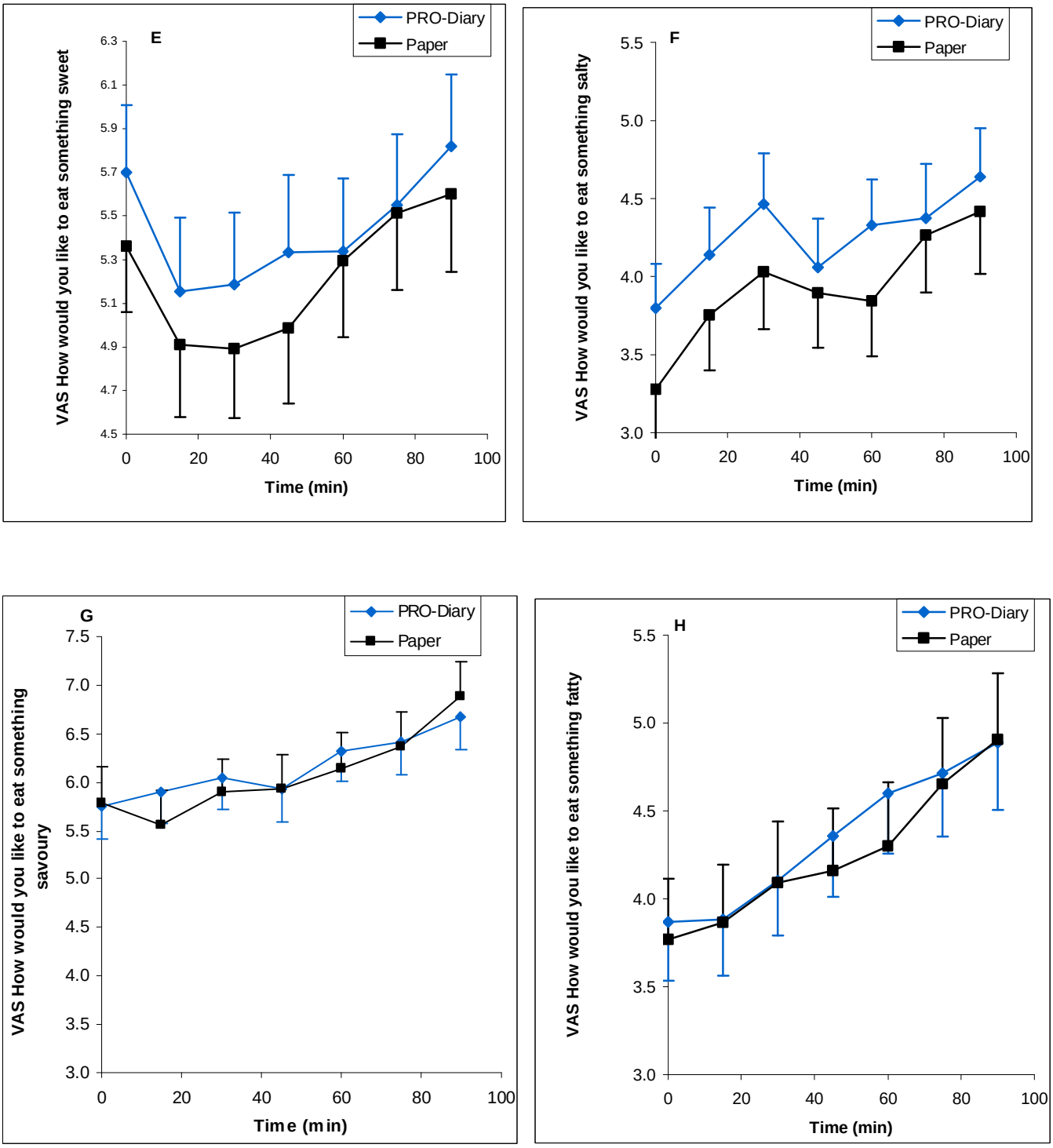


Figure 2. VAS scores for how hungry do you feel (A), how much can you eat (B) and how full do you feel (C), how thirsty do you feel (D), would you like something sweet (E), would you like something savoury (F), would you like something salty (G), would you like to eat something fatty (H) recorded on the PRO-Diary and paper questionnaires (mean ± SEM).

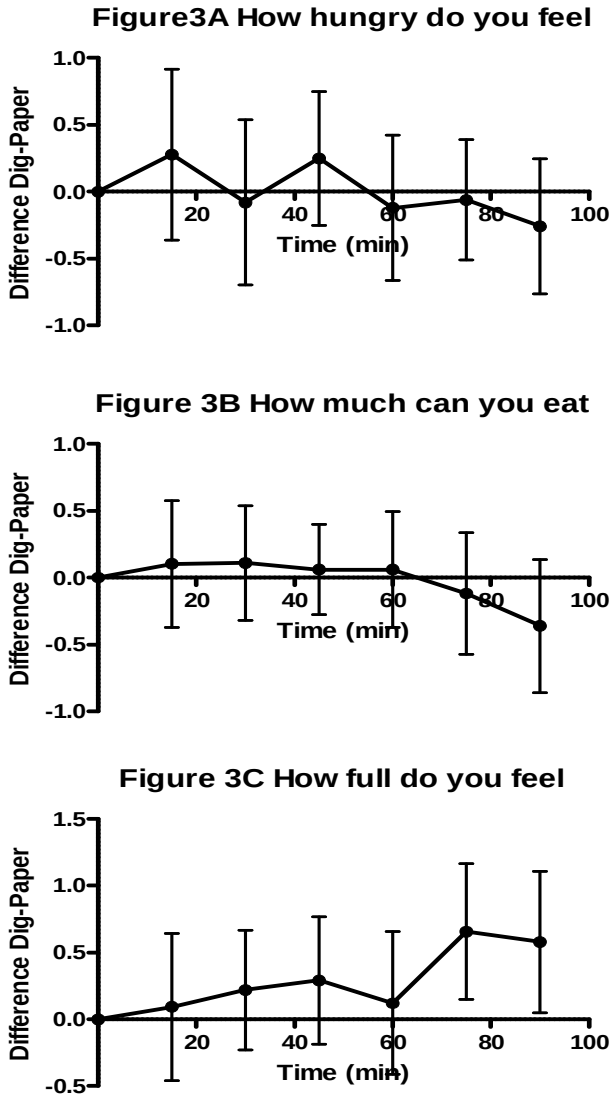


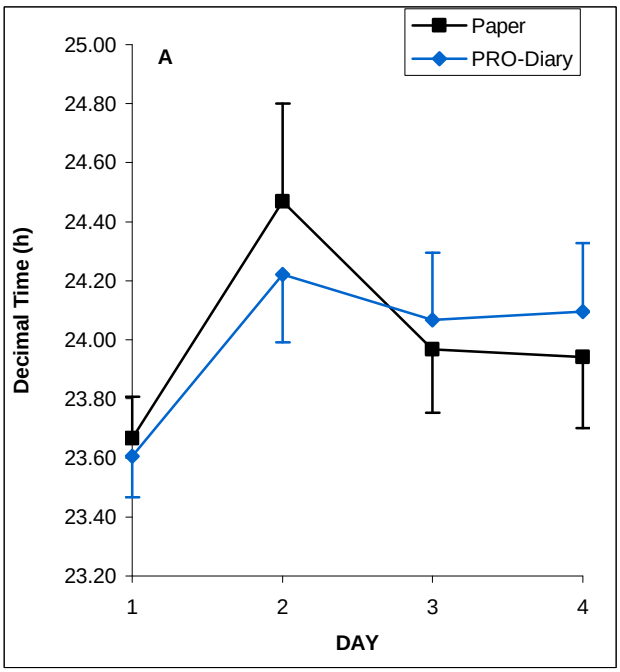
Figure 3A, B, C. Difference between PRO-Diary minus paper VAS scores in response to how hungry do you feel, how much you can eat, how full do you feel. (Mean ± 95% confidence limits).

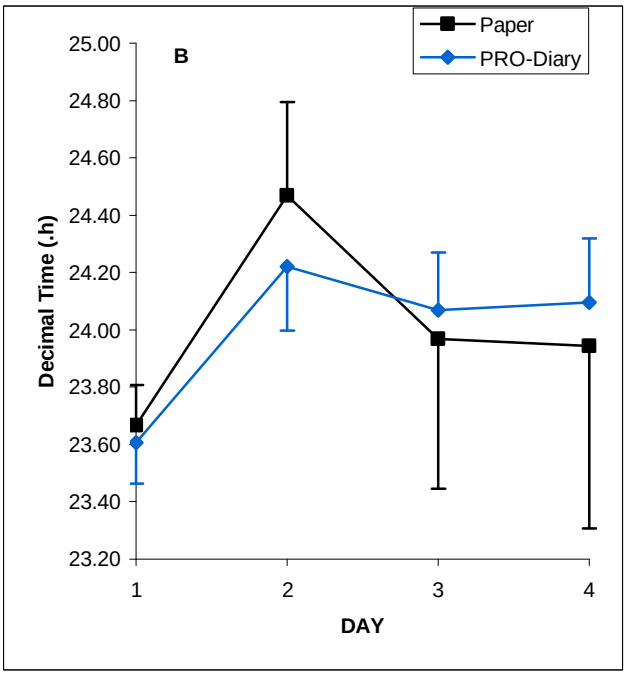
Analysis of sleep questionnaires

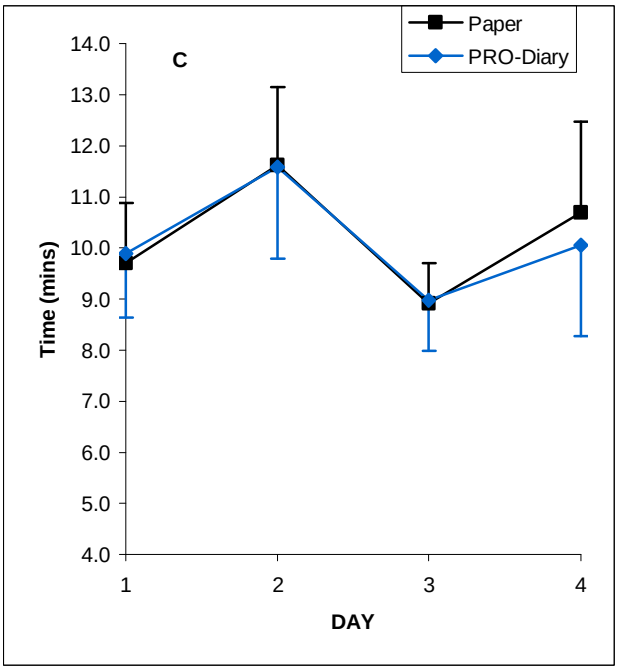
Sleep Diaries

The subjects were assessed for the following criteria:- What time did you go to bed, what time did you try and sleep, sleep latency, how many times did you wake up, what was the reason for waking up, what time did you wake up, what time did you turn on the light, what time did you get up, is this a typical night, if permitted could you have sleep longer, and how do you

rate you sleep. The Two way RM-ANOVA showed a significant effect of time for all observations. Figure 5 show graphs of some of the sleep parameters. No significant difference was observed in all parameters between the PRO-Diary and paper questionnaires except when the light went on in the morning (p=0.04) with the paper diary responses being consistently lower than the PRO-Diary.







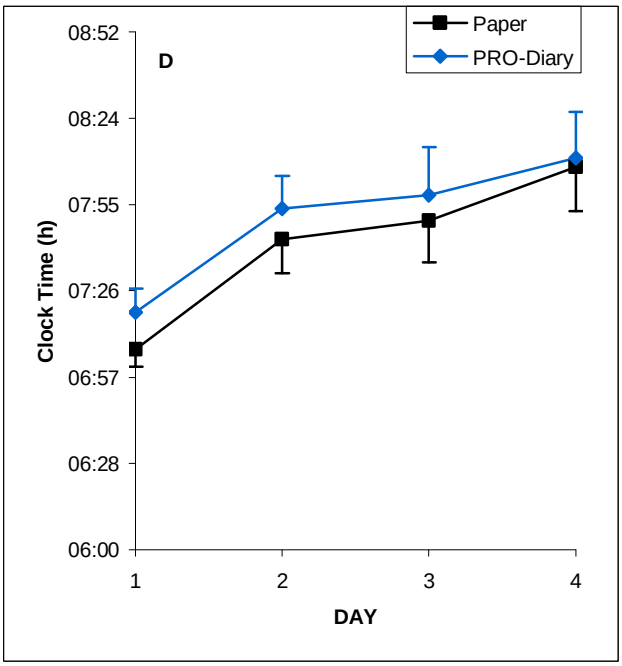


Figure 5: Sleep parameters during the trial. (A) Bedtime, (B) Try to Sleep, (C) Sleep latency (D) Light on time (mean ± SEM)

Analysis of mood and alertness

VAS scales for mood and alertness which included Karolinska Sleepiness scale, subjective alertness, calmness, cheerfulness and depression were assessed by two way repeated measured ANOVA at each of the three time points (0900h,1400h,2100h) for 5 days during the study . No significant differences were observed for all observations across the day except for Karolinska Sleepiness scale (KSS) (p=0.016) and how calm do you feel (p=0.016) both at 2100.

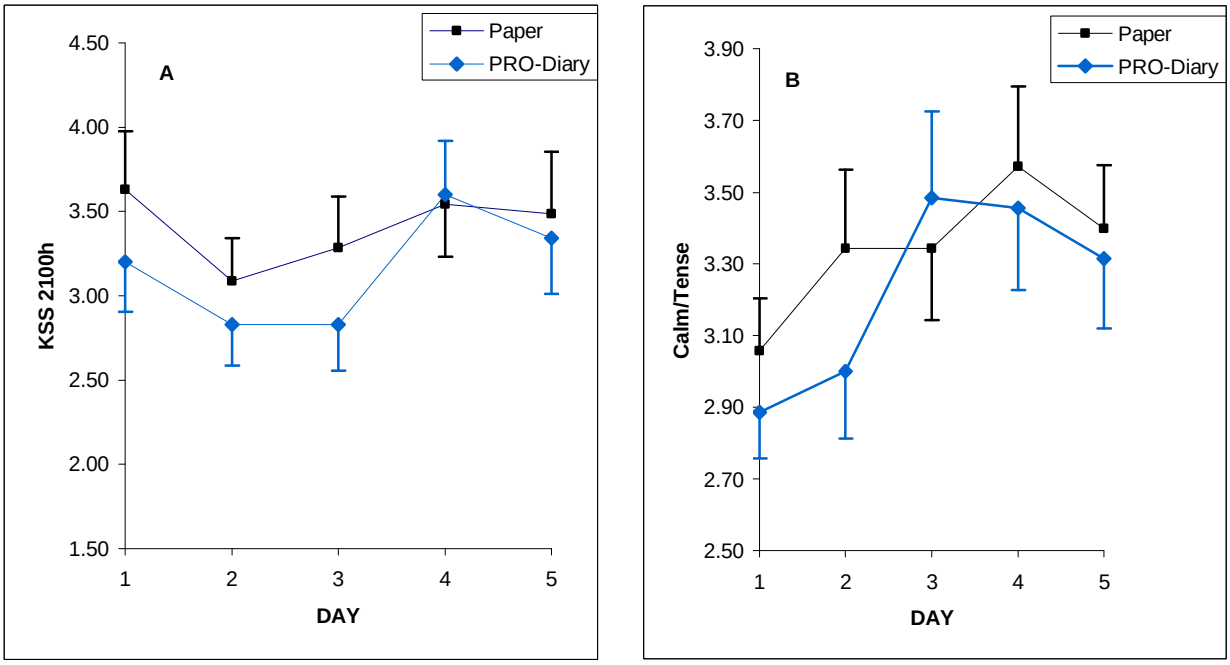


Figure 6. Subjective day time mood and alertness (A) 2100h KSS and 9-digit scales for (B) 21:00h calmness (mean ± SEM)

Discussion

All subject found the PRO-Diary easy to use. Problems occurred on occasions when subjects pressed to access the mood and alertness questionnaire. Comments such as they attempted to access the questionnaire but the questionnaire disappeared from the menu were reported. On a

few occasions the PRO-Diary did not respond and results had to be downloaded. The diaries were then reloaded with the questionnaire.

Volunteers who are in the nutrition and dietetics area of research found them very useful and are at present using the diaries in undergraduate studies within the Faculty.

Food Visual Analogue Scales

Loss of food satiety data occurred on nine occasion using the PRO-Diary resulting in 63 observations (2.6%) versus 10 observations (0.41%) for the paper questionnaire on the food VAS data. This was entirely due to subjects forgetting to complete the Pro-Diaries at the required time even though the times had been written down in front of each subject.

Overall there was no differences in the food VAS scoring for all criteria except how full do you feel. Plotting the difference between the PRO-Diary minus the paper questionnaire data with error bars representing 95% confidence limits is the most useful way of presenting the data. These graphs demonstrated no consistent pattern of disagreement between the three major outcomes**.** There was a trend towards differences between the two methods in the recorded observations from participants in responses to how full do you feel occurred after 60minutes. However the PRO-Diary data returned to baseline levels whereas the paper diary showed responses well below baseline levels. So it could be argued that the PRO-Diary gave accurate result.

Sleep questionnaires

There was a loss of data from the both sleep PRO-Diary and paper questionnaires during the study; there seemed to be a lack of ability of some subjects to understand the aim of the study and therefore only 42 subjects could be used for statistical analysis. However there were no significant differences between measuring sleep using the two methods. Although differences

were observed in the when did you turn the light on, this question was not applicable during the time of year the study was completed since it was light when the subjects woke up.

Mood and Alertness questionnaire

Twenty one observations were required to be recorded during the study and each of these had to be recorded on both the PRO-Diary and paper questionnaires. However as with the sleep questionnaire there was a loss of data. A complete set of data was obtained from 34 subjects for all the observations for 5 days during the study (15 observations for each individual). Two observations were found to be statistically significant between the PRO-Diary and paper questionnaire this was for the KSS and subjective calmness both at the 2100h time-point. The differences occurred in the early days of the study (days 1-3) and could be due to familiarisation of the subjects with the Pro- Diary.