STATISTICAL ANALYSIS PLAN

FOR iSupport WS1

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Version: 1

Statistical analysis plan (SAP) for Work Stream 1 (WS1) of 'A randomised controlled trial and feasibility study of the effects of an e-health intervention 'iSupport' for reducing distress of dementia carers, especially in the ongoing pandemic of COVID-19' (iSupport)

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Document History

Updated version no.	Effective date	Authorship	Section changed	Summary of changes
1	23/10/2023	N. Goulden	New	

Acronyms and definition of terms

Acronym	Meaning
CONSORT	Consolidation Standards Of Reporting Trials
IDMC	Independent Data Monitoring and Committee
ITT	Intention-To-Treat analysis
NICE	National Institute for Health and Care Excellence
NWORTH	North Wales Organisation for Randomised Trials in Health
RCT	Randomised Controlled Trial
SAP	Statistical Analysis Plan
TSC	Trial Steering Committee
UK	United Kingdom
WS	Workstream

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1. Statistical analysis plan authorship

The analysis plan has been authored by Nia Goulden, Trial Statistician. There has also been input from Dr Zoë Hoare (Principal Statistician), Greg Flynn (Trial Manager), and Professor Gillian Windle (Chief Investigator). The draft plan will be circulated to the IDMC and TSC for comments before being signed off. All of the statistical analysis will be completed by Nia Goulden and overseen by Dr Zoë Hoare.

2. Introduction

2.1 Background and Rationale

Estimates suggest 850,000 people in the UK live with dementia. Most (700,000) are cared for at home (1), supported by a family member or friend who has little knowledge of the condition and how to best manage it. There is a well-documented detrimental impact of caregiving on the physical and mental health of dementia carers. Despite this detrimental impact to carers, informal care benefits their relatives and also society. Access to appropriate, useful, low-cost, effective support for carers, with effective implementation strategies, is a priority for people living with dementia, their carers and service providers, and the focus of this research.

2.2 Research Questions

1. Is carer distress and/or symptoms of depression (primary outcomes) significantly reduced in participants randomly allocated to receive 'iSupport' compared to participants allocated to receive standardised information?

2. Are symptoms of anxiety (secondary outcome) significantly reduced, and resilience, relationship quality, the quality of life of the person living with dementia and dementia knowledge (secondary outcomes) significantly increased in participants allocated to receive 'iSupport' compared to participants allocated to a comparison group receiving standardised information about dementia?

3.Is the health-related quality of life of the person with dementia increased when carers are allocated to receive 'iSupport' compared to carers allocated to a comparison group receiving standardised information about dementia?

2.3 Trial Design

Participants from Wales, England and Scotland will be randomised to receive either the iSupport intervention or a booklet from the Alzheimer's society. The trial

statistician and research assistants will be blinded to group allocation, participants and other members of the trial team will be unblinded to group allocation.

WS1 is a definitive pragmatic individually randomised controlled trial across Wales, Scotland and England, with a six-month nested internal pilot. This will:

- Determine progression of the definitive trial based on a go/review/stop criteria (nested internal pilot – covered in iSupport Internal Pilot Analysis Report v1);
- Determine the effectiveness of 'iSupport' in reducing symptoms of distress;
- Determine the effectiveness of 'iSupport' in reducing symptoms of depression and anxiety;
- Determine the effectiveness of 'iSupport' in improving dementia knowledge, relationship quality and resilience;
- Describe the trial sample according to demographic/socioeconomic characteristics.

2.4 iSupport Intervention

'iSupport' is an internet-based psychoeducation and skills development intervention. The theoretical underpinnings of 'iSupport' are based on person-centred care, which recognises that dementia care should reflect the individual's needs, personality and ability (2). These elements are integrated into the interactive content of 'iSupport'. The self-care techniques are based on theoretically informed programmes with some evidence for benefits, including psychoeducation, relaxation, behavioural activation, cognitive reframing, and problem-solving (2).

'iSupport' consists of five main themes and twenty-three accompanying exercises, namely: (i) introduction to dementia; (ii) being a carer; (iii) caring for me; (iv) providing everyday care; and (v) dealing with behaviour changes. Each exercise takes approximately 5-15 minutes and follows the same format: information about a topic presented; short interactive exercises and questions with instant feedback on responses; a summary of the lesson; a relaxation exercise.

'iSupport' is based on personal choice: carers can construct their own personalised plan and access which sessions they feel are most relevant to them at that point in time. It is anticipated the whole programme can be completed in 3 months. The programme can be followed via the internet using a personal computer or a tablet (e-health), or through a mobile phone accessing a 'mobile friendly' version of the platform (m-health).

2.5 Study Population

Inclusion Criteria

1) Adults (18+) who self-identify as an unpaid carer (partners, children, friends, etc.) of a person with dementia who is not living in a full-time care facility, caring at least weekly for at least 6 months.

2) Self-identify as experiencing at least some stress, depression or anxiety.

3) The care recipient has to have a confirmed diagnosis of dementia (through self-report of the carer, to reflect the 'real world' application of 'iSupport').

Exclusion Criteria

1) Receiving psychological treatment from a mental health specialist at the time of recruitment.

2) Unable to comprehend written English.

3) No access to the internet.

4) Unable to give informed consent to the trial.

5) Have previously used 'iSupport' materials (in the last 12 months).

3. Statistical Principles

3.1 Sample size justification

Both primary outcomes (Zarit Burden scale and CES-D10) are important to the participants and have potential to indicate an effect, a successful trial would be one which detected an effect in either of these outcomes. Therefore, the sample size has been approached considering these as multiple primary endpoints at six months.

The Portuguese RCT of 'iSupport' has set an effect size of 0.5 (3) and a meta-analysis of multicomponent interventions for carers found a standardized effect size of 0.65 [CI=0.46-0.84] for the ZBI (4). Being conservative we have assumed a standardised effect size of 0.4 for the ZBI, which is equivalent to a 4-point difference on the scale and assuming a standard deviation of 10 as derived from scale validation with dementia carers (5).

Meta-analysis by Leng et al. (6) indicated that the standardised effect size possible for the CES-D10 would be in the order of 0.2. Ying et al. (7) denote that the correlation between these two measures is approximately 0.7.

Using the multiple primary endpoint estimator in the R package mpe with power of 90% and significance set to 2.5% established a sample of 262 would be required to have the potential to detect an effect in at least one of these outcomes. The mpe package uses the methodology of Sugimoto et al. (8) and Suzo (9) to estimate the

sample size required based on the defined effect sizes and the correlation between the measures. The attrition rate is estimated as 25%, based on 9 dementia intervention studies, where the mean retention rate was 15.33% (range 2%-24%). Accommodating a 25% attrition rate by six months, we will need to recruit and randomise 350 participants.

3.2 Randomisation

Randomisation will be achieved online, through the remote randomisation centre at NWORTH at Bangor University. Once baseline measures have been completed, the participant details will be submitted to the online NWORTH system and the participant randomised to either the intervention or comparison group. This will be done using a 1:1 ratio of intervention:comparison and will be stratified by site (Wales, England, Scotland), age (18-40, 41—50, 51-60, 61-70, 71-80, 80+) and gender (Male, Female, Other). The randomisation system will use a dynamic adaptive allocation algorithm (10). This algorithm minimises the group imbalance in total, for each stratification variable and each strata (combination of stratification variables), by calculating a probability for selecting each group, based on the imbalance in total, within stratification variables and within strata, and then generating a random number to allocate the groups based on those probabilities. Concealment of allocation for the participants will not be possible due to the nature of the intervention.

3.3 Levels of confidence

For the ZBI and CES-D10, all applicable statistical tests will be two-sided and will be performed considering a 2.5% significance level, to account for multiple testing, and all confidence intervals presented will be 97.5%. For other outcome measures a 5% significance level will be used.

3.4 Protocol Violations and deviations

The definition of a protocol violation is an intended failure to adhere to the protocol such as wrong treatment being prescribed or administered or incorrect data being collected and documented. A protocol deviation is an unintended failure to adhere to the protocol; examples include errors in applying inclusion/exclusion criteria or missed follow-up visits due to error. A table containing any protocol violations or deviations will be summarised within the final analysis.

3.5 Missing Data

For missing items within an outcome measure, any published guidelines for that outcome measure will be utilised. Otherwise, in accordance with guidelines by Bono and colleagues (11), if the number of missing items on an outcome measure is 20% or

less, the missing value for the item will be substituted by the individual's mean score. Otherwise no score will be calculated for that instance of the outcome measure.

For multiple imputation, the number of imputations will be dependent on the percentage of missing data (12). Multiple imputation will be completed in Stata (13), and will include the factors and covariates which are to be included in the analysis models. If the percentage of missing data is less than 5%, no multiple imputation will be performed and analysis will be based on complete case.

3.6 Outliers

Outliers identified from the statistical analyses will be examined by rechecking the data. No outliers will be discarded if they can be verified as being correct from source data and checking with the researchers, or are within range. If any outliers are dropped from the dataset it will be reported and full reasoning given.

4. Data

For full details on the data collection, flow and storage please refer to the current version of the iSupport Data Management Plan.

4.1 Proposed clinical outcomes

All outcomes will be collected at baseline, three month follow up and six month follow up, except in cases where the care recipient has passed away, in which case a shorter version of the T1 or T2 CRF is used to minimise carer distress. There are two primary outcome measures for WS1:

1. Zarit Burden Interview (ZBI) (14); and
2. Centre for Epidemiological Studies of Depression Scale (CES-D10) (15,16).

Secondary outcome measures for WS1 are:

1. Generalised Anxiety Disorder Questionnaire (GAD-7) (17);
2. Resilience Scale-14 (RS-14) (18);
3. Quality of the carer-patient relationship (QCPR) (19)
4. Measure of dementia knowledge (DKAS) (20);
5. DEMQOL-Proxy (21);
6. Following feedback from the funding panel, we will evaluate the impact on the health-related quality of life of the person being cared for, with the DEMQOL-

Proxy. This is a widely-used instrument for measuring the health-related quality of life of people living with dementia, completed by the carer. It is adapted for use as a preference-based measure in economic evaluations.

4.2 Definitions and calculations of outcome measures

The data collected will include the measures outlined in the previous section. See the table in appendix 1 for full details.

4.3 Unblinding

The final unblinding for results will take place after all blinded analysis have been completed. The analyses which will need to be completed unblinded are specified in Section 5.4. The unblinding form (found in the Appendix of SOP 5.03 Randomisation systems) will be completed by the trial statistician and handed to the NWORTH IT team who will then provide the group details. The allocations will be revealed at a results meeting which may include members of the TMG, IDMC and TSC.

5. Statistical analyses

5.1 Analysis Time Frame

TASK	EXPECTED DATE
First participant recruited	7th December 2021
Final participant recruited	31st March 2023
Final follow up completed	30th September 2023
Data cleaning completed	31st October 2023
Analysis completed	31st December 2023

5.2 Recruitment and retention

The analysis will consider the items from the CONSORT checklist (22) to ensure that all topics are being covered. Values for eligibility rates, recruitment rates, attrition rates and withdrawal rates will be reported using the flow data collected within the study. This will be evaluated overall and per group.

Furthermore, details on reasons for ineligibility and non-recruitment will be reported within a table along with their related patient frequencies and percentages. Information on withdrawals and non-respondents will be presented including reasons where applicable and time points during the trial.

5.3 Descriptive statistics

Descriptive statistics of the data will be presented. All continuous measures will be reported with mean values and standard deviations provided that data are normally distributed, otherwise the median and interquartile range will be used. Categorical variables will be reported with counts and related percentages.

5.4 Outcome Measures

All analysis will be guided by the principle of intention to treat. This means that data will be analysed with participants in the group they were allocated to by the randomisation algorithm, regardless of whether they received the allocated intervention or not.

Linear Mixed Models

All outcome measures are collected at baseline, three month follow up and six month follow up, unless the person with dementia is deceased post-baseline. In this instance some of the outcome measures are not completed, and the data they have provided will be analysed with the data for other carers. Outcome measures will be analysed using a linear mixed model with the data at all three time points. Age will be included as a covariate, gender (male, female, Other, No answer) as a factor and site (Wales, England, Scotland) as a random effect. Including site as a random effect means that we can account for the variance among the values at the different sites, as opposed to testing for differences between sites. The allocated group, time (baseline, three month follow up, six month follow up) and a time*group interaction will also be included. The covariance will be modelled as independent and identically distributed Gaussian within-group errors with one common variance. Effect sizes will be estimated using adjusted mean differences from the model, standard errors and 95% confidence intervals.

Sensitivity analysis for iSupport use

The study application and protocol state that complier average causal effect will be completed, with compliance defined by the number of times that the participant has logged in to iSupport. Since there are no instructions to participants regarding expected use of iSupport, it is not possible to define a complier in this context. Therefore, to allow an analysis of participants interaction with iSupport we will conduct an alternative analysis.

For each outcome measure the linear mixed effects model will be repeated, as described previously, but additionally including number of times logged in to iSupport, number of modules completed and number of activities completed as factors, and length of time spent using iSupport as a covariate. The purpose of this is to determine whether the number of time logged on, number of modules completed, number of activities completed, and length of time spent using iSupport, have an impact on the outcome measures.

Effect sizes will be estimated using adjusted mean differences from the model, standard errors and 95% confidence intervals. Note that sensitivity analysis for iSupport use will need to be completed when the trial statistician has been unblinded, since executing this analysis will identify which group is the intervention group.

Sensitivity analysis for site

The linear mixed models will be repeated without site included, to determine whether the treatment effect varies by site. Since iSupport is a self-completed intervention,

which participants complete as they wish to suit their own schedule and needs, there will be no difference to delivery of the intervention based on where the participant lives.

Age will be included as a covariate, gender (male, female, Other, No answer) as a factor. Including site as a random effect means that we can account for the variance among the values at the different sites, as opposed to testing for differences between sites. The allocated group, time (baseline, three month follow up, six month follow up) and a time*group interaction will also be included. Effect sizes will be estimated using adjusted mean differences from the model, standard errors and 95% confidence intervals.

Sensitivity analysis for language

If there are at least 60 participants randomised from Wales, and at least 30 of them had their interviews conducted in Welsh, a sensitivity analysis will be conducted in order to assess the impact of completing the outcome measures in Welsh instead of English. The reason for this is to determine whether the language to complete the interview makes a difference to the outcomes. The same linear mixed model described previously will be applied to assess this, with the addition of a variable to indicate whether the interview was completed in English or Welsh.

5.5 Check of Assumptions

A check of the assumptions required of the statistical tests will be performed.

Linear Mixed Models

For the linear mixed effects model we will check that the residuals of the models are approximately multivariate normally distributed and that there is homogeneity of variance. The assumed covariance matrix will be the independent covariance matrix. A scatterplot will be produced of the standardised residuals against the predicted values to test for homoscedasticity. In the event of these assumptions being violated we will consider transforming the data in order to satisfy the assumptions of the test. In the event of the residuals being skewed to the right, or the variance increasing with an increasing independent variable, a transformation using a lower power, such as square root, cube root or a log transformation will be used. In the event of the residuals being skewed to the left, or variance decreasing with increasing independent variable, a transformation using a higher power, such as square root or cube root transformation will be used. This should also address any violations of non-normality of data or homogeneity of variance.

We will need to produce scatterplots of the covariates against the dependent variables for each level of the independent variables. This should show a linear relationship between the covariate and dependent variable. The lines of best fit should be parallel, so that there is no interaction between the covariate and the independent variable. In the event of this assumption being violated it will be necessary to add the interaction term of the covariate and dependent variable to the linear mixed effects model.

In the event of the assumptions of linear mixed model not being met we will also consider use of a generalised linear model with gamma distribution and inverse link function in the first instance. If the generalised linear model with gamma distribution and inverse link function are not appropriate to satisfy the violations of assumptions of the linear mixed model then alternative distributions and link functions will be considered.

6. Software

All quantitative analysis will be completed using SPSS, Stata and R.

7. References

1. The Trajectory of Dementia in the UK - Making a Difference [Internet]. [cited 2021 May 24]. Available from: https://www.ohe.org/publications/trajectory-dementia-uk-making-difference
2. Pot AM, Gallagher-Thompson D, Xiao LD, Willemse BM, Rosier I, Mehta KM, et al. iSupport: a WHO global online intervention for informal caregivers of people with dementia [Internet]. Vol. 18, World Psychiatry. Blackwell Publishing Ltd; 2019 [cited 2021 May 24]. p. 365–6. Available from: https://pubmed.ncbi.nlm.nih.gov/31496096/
3. Teles S, Ferreira A, Seeher K, Fréel S, Paúl C. Online training and support program (iSupport) for informal dementia caregivers: Protocol for an intervention study in Portugal. BMC Geriatr [Internet]. 2020 Jan 8 [cited 2021 May 24];20(1):1–13. Available from: https://doi.org/10.1186/s12877-019-1364-z
4. Sörensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? an updated meta-analysis. Gerontologist [Internet]. 2002 [cited 2021 May 24];42(3):356–72. Available from: https://pubmed.ncbi.nlm.nih.gov/12040138/
5. Higginson IJ, Gao W, Jackson D, Murray J, Harding R. Short-form Zarit Caregiver Burden Interviews were valid in advanced conditions. J Clin Epidemiol [Internet]. 2010 May [cited 2021 May 24];63(5):535–42. Available from: https://pubmed.ncbi.nlm.nih.gov/19836205/
6. Leng M, Zhao Y, Xiao H, Li C, Wang Z. Internet-based supportive interventions for family caregivers of people with dementia: Systematic review and meta-analysis [Internet]. Vol. 22, Journal of Medical Internet Research. JMIR Publications Inc.; 2020 [cited 2021 May 24]. p. e19468. Available from: https://www.jmir.org/2020/9/e19468
7. Ying J, Yap P, Gandhi M, Liew TM. Validity and Utility of the Center for Epidemiological Studies Depression Scale for Detecting Depression in Family Caregivers of Persons with Dementia. Dement Geriatr Cogn Disord [Internet].

2019 Oct 1 [cited 2021 May 24];47(4–6):323–34. Available from: https://pubmed.ncbi.nlm.nih.gov/31307034/

8. Sugimoto T, Sozu T, Hamasaki T. A convenient formula for sample size calculations in clinical trials with multiple co-primary continuous endpoints. Pharm Stat [Internet]. 2012 Mar [cited 2021 May 24];11(2):118–28. Available from: https://pubmed.ncbi.nlm.nih.gov/22415870/
9. Sozu T, Sugimoto T, Hamasaki T, Evans SR. Sample Size Determination in Clinical Trials with Multiple Endpoints. Sample Size Determination in Clinical Trials with Multiple Endpoints. Springer Heidelberg; 2015. 1–95 p.
10. Russell D, Hoare ZSJ, Whitaker R, Whitaker CJ, Russell IT. Generalized method for adaptive randomization in clinical trials. Stat Med. 2011;30(9):922–34.
11. Bono C, Ried LD, Kimberlin C, Vogel B. Missing data on the Center for Epidemiologic Studies Depression Scale: A comparison of 4 imputation techniques. Research in Social and Administrative Pharmacy [Internet]. 2007 Mar [cited 2021 May 17];3(1):1–27. Available from: https://pubmed.ncbi.nlm.nih.gov/17350555/
12. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. Stat Med. 2011;
13. Carlin JB, Galati JC, Royston P. A new framework for managing and analyzing multiply imputed data in Stata. Stata Journal [Internet]. 2008 [cited 2021 May 17];8(1):49–67. Available from: http://www.stat.psu.edu/
14. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'donnell M. The Zarit Burden Interview: A new short version and screening version. Gerontologist [Internet]. 2001 Oct 1 [cited 2021 Mar 30];41(5):652–7. Available from: https://pubmed.ncbi.nlm.nih.gov/11574710/
15. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. Appl Psychol Meas [Internet]. 1977 Jul 26 [cited 2021 May 24];1(3):385–401. Available from: https://journals.sagepub.com/doi/10.1177/014662167700100306
16. Andresen EM, Byers K, Friary J, Kosloski K, Montgomery R. Performance of the 10-item Center for Epidemiologic Studies Depression scale for caregiving research. SAGE Open Med [Internet]. 2013 Jan [cited 2021 Mar

30];1:205031211351457. Available from: https://pubmed.ncbi.nlm.nih.gov/26770693/

17. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. Arch Intern Med [Internet]. 2006 May 22 [cited 2021 Mar 30];166(10):1092–7. Available from: https://pubmed.ncbi.nlm.nih.gov/16717171/
18. Wagnild G. The Resilience Scale User's Guide for the US English version of the Resilience Scale and the 14-item Resilience Scale (RS-14). The Resilience Center, Montana. 2009;
19. Spruyette N, van Audenhove C, Lammertyn F. Internal Report: The Scale for the Quality of the Current Relationship. Leuven: LUCAS-KULeuven. 2000;
20. Annear MJ, Toye C, Elliott KEJ, McInerney F, Eccleston C, Robinson A. Dementia knowledge assessment scale (DKAS): Confirmatory factor analysis and comparative subscale scores among an international cohort. BMC Geriatr [Internet]. 2017 Jul 31 [cited 2021 Mar 30];17(1). Available from: https://pubmed.ncbi.nlm.nih.gov/28760154/
21. Mulhern B, Rowen D, Brazier J, Smith S, Romeo R, Tait R, et al. Development of DEMQOL-U and DEMQOL-PROXY-U: Generation of preference-based indices from DEMQOL and DEMQOL-PROXY for use in economic evaluation. Health Technol Assess (Rockv) [Internet]. 2013 [cited 2021 Mar 30];17(5):1–160. Available from: https://pubmed.ncbi.nlm.nih.gov/23402232/
22. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. International Journal of Surgery. 2012;10(1):28–55.

Referenced documents:

1. iSupport Data Management Plan

8. Appendices

Appendix 1 – Validated outcome measures summary table

Outcome measure	Definition	Scoring	Subscales	Missing value rules	Thresholds
ZBI	Questions asking carer about how they feel when taking care of another person	Scales 0 = Never to 4 = Nearly Always. The total score is the sum of the item scores.	None	None	None
CES-D10	Questions about mood and how a person may have behaved	Scales 0 = Rarely or none of the time to 3 = Most or all of the time. The total score is the sum of the item scores.	None	None	None
GAD-7	Questions to determine whether they have been bothered by symptoms of anxiety in the past two weeks	Scale from 0 = Not at all to 3 = Nearly every day. The total score is the sum of the item scores.	None	None	0 – 4 = None 5 – 9 = Mild Anxiety 10 – 14 = Moderate Anxiety 15 – 21 = Severe Anxiety
RS-14	Questions about resilience	Scales 1 = Strongly Disagree to 7 = Strongly Agree. The total score is the sum of the item scores.	None	None	None

Outcome measure	Definition	Scoring	Subscales	Missing value rules	Thresholds
QCPR	Questions about the quality of the relationship between the carer and the person they care for	Scales 1 = Totally Disagree to 5 = Totally Agree. The total score is the sum of the item scores.	Warmth subscale – questions 1, 4, 5, 6, 7, 9, 12, 14 Criticism and conflict subscale – questions 2, 3, 8, 10, 11, 13	None	None
DKAS	Questions to determine knowledge of and attitude towards dementia	Scales 1 = False to 4 = True, with an option of 5 = I don't know. Questions need to be rescored depending on whether the statement is true or false. The total score is the sum of the recoded item scores.	Causes and characteristics subscale – questions 1, 2, 3, 4, 5, 6, 7 Communication and behaviour subscale – questions 14, 15, 16, 17, 18, 19 Care considerations subscale – questions 20, 21, 22, 23, 24, 25 Risks and health promotion subscale – questions 8, 9, 10, 11, 12, 13	None	None

Outcome measure	Definition	Scoring	Subscales	Missing value rules	Thresholds
DEMQOL-Proxy	Questions about mood and how a person may have behaved	Scales 1 = A lot to 3 = Not at all. The total score is the sum of the item scores.	None	Rules for computing a score with 50% of items missing and 20% of items missing. Missing items are replaced with pro-rated values from non-missing questions.	None