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## Quality of motivational interviewing matters: the effect on participation in health-promotion activities in a cluster randomized controlled trial1

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#### Supplementary tables

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**Table S1 1**. **CONSORT 2010 checklist for reporting a cluster randomized trial.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Section/Topic | Item No | Standard Checklist item | Extension for cluster designs | Page No or paragraph |
| Title and abstract | | | |  |
|  | 1a | Identification as a randomized trial in the title | Identification as a cluster randomized trial in the title | Done |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | See table 2 | These were all included in the abstract. |
| Introduction | | | |  |
| Background and objectives | 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | “objectives”, and “design” |
| 2b | Specific objectives or hypotheses | Whether objectives pertain to the the cluster level, the individual participant level or both | “objectives” |
| Methods | | | |  |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Definition of cluster and description of how the design features apply to the clusters | “objectives” and previous publication on trial designa |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  | “design” |
| Participants | 4a | Eligibility criteria for participants | Eligibility criteria for clusters | “sample” |
| 4b | Settings and locations where the data were collected |  | “design” |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Whether interventions pertain to the cluster level, the individual participant level or both | “intervention” |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Whether outcome measures pertain to the cluster level, the individual participant level or both | “measures” and “analyses” |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  | Not applicable |
| Sample size | 7a | How sample size was determined | Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty | “data analyses” |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  |  |
| Randomization: | | | |  |
| Sequence generation | 8a | Method used to generate the random allocation sequence |  | Previous publication on trial designa |
| 8b | Type of randomization; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | “Design”, and previous publication on trial designa |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both | “Design”, and previous publication on trial designa |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replace by 10a, 10b and 10c |  |
|  | 10a |  | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | “Design”, and previous publication on trial designa |
|  | 10b |  | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling) | “Design” and “Sample” |
|  | 10c |  | From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomization | “Design” and previous publication on trial designa |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  |  |
| 11b | If relevant, description of the similarity of interventions |  | “Intervention” |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | How clustering was taken into account | “Analyses” |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  | “Analyses” |
| Results | | | |  |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome | For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome | Figure 1, table 1 |
| 13b | For each group, losses and exclusions after randomization, together with reasons | For each group, losses and exclusions for both clusters and individual cluster members | Figure 1, “sample” |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  | “design” |
| 14b | Why the trial ended or was stopped |  | Not applicable |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Baseline characteristics for the individual and cluster levels as applicable for each group | Table 1, “sample”, “results” |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | For each group, number of clusters included in each analysis | Figure 1 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome | “results”, and additional file 2 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |  | These were included |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |  | “results” |
| Harms | 19 | All important harms or unintended effects in each group |  | Not applicable |
| Discussion | | | |  |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  | “discussion” |
| Generalizability | 21 | Generalizability (external validity, applicability) of the trial findings | Generalizability to clusters and/or individual participants (as relevant) | “discussion” |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  | “discussion” |
| Other information | | |  |  |
| Registration | 23 | Registration number and name of trial registry |  | “design” |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  |  |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders |  | “acknowledgmenents” |

# aTessa A. Kouwenhoven-Pasmooij, Bosiljka Djikanovic, Suzan J. W. Robroek, Pieter Helmhout, Alex Burdorf, M.G. Myriam Hunink. Design and baseline characteristics of the PerfectFit study: a multicenter cluster-randomized trial of a lifestyle intervention in employees with increased cardiovascular risk. BMC Public Health 2015 **15**:715

**Extension of CONSORT for abstractsto reports of cluster randomized trials**

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Standard Checklist item | Extension for cluster trials |  |
| Title | Identification of study as randomized | Identification of study as cluster randomized | Included |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) |  | Included |
| Methods |  |  |  |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Eligibility criteria for clusters | Included |
| Interventions | Interventions intended for each group |  | Included |
| Objective | Specific objective or hypothesis | Whether objective or hypothesis pertains to the cluster level, the individual participant level or both | Included |
| Outcome | Clearly defined primary outcome for this report | Whether the primary outcome pertains to the cluster level, the individual participant level or both | Included |
| Randomization | How participants were allocated to interventions | How clusters were allocated to interventions | Included |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment |  | Not in abstract |
| Results |  |  |  |
| Numbers randomized | Number of participants randomized to each group | Number of clusters randomized to each group | Included in manuscript, fig 1 and “sample” and “results” |
| Numbers analyzed | Number of participants analyzed in each group | Number of clusters analyzed in each group | Included |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Results at the cluster or individual participant level as applicable for each primary outcome | Included |
| Harms | Important adverse  events or side effects |  | Not applicable |
| Conclusions | General interpretation of the results |  | Included |
| Trial registration | Registration number and name of trial register |  | Included |
| Funding | Source of funding |  | In manuscript, “acknowledgments” |

**Table S2: Quality of MI including intercoder-differences.**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Scoring: | Item: | Aggregated ratings  of both coders | | Average rating by  Coder 1 | | Average rating by  Coder 2 | | Interrater-reliability | |
|  |  | Mean | SD | Mean | SD | Mean | SD | Intra-class correlation coefficient | 95% CI |
| **Behavior counts:** | Percentage open questions | 34.90 | 11.93 | 33.42 | 16.22 | 36.37 | 20.48 | 0.71 | 0.49-0.84 |
|  | Percentage complex reflections | 63.92 | 14.33 | 65.77 | 19.89 | 62.06 | 22.55 | 0.75 | 0.560.87 |
|  | Percentage MI adherent | 84.16 | 9.30 | 85.21 | 13.16 | 83.12 | 17.23 | 0.51 | 0.22;0.72 |
|  | Reflection to question ratio | 1.43 | 0.62 | 1.35 | 1.15 | 1.50 | 1.45 | 0.69 | 0.48;0.83 |
| **Global scores** a**:** | Empathy (1-5) | 3.31 | 0.60 | 3.66 | 0.87 | 2.97 | 1.15 | 0.28 | -0.05;0.56 |
|  | Spirit (1-5) | 3.44 | 0.51 | 3.76 | 0.88 | 3.12 | 1.20 | 0.34 | 0.01;0.60 |
|  | Direction (1-5) | 4.31 | 0.47 | 4.17 | 0.98 | 4.46 | 0.92 | 0.60 | 0.34;0.77 |
|  | Mean global (1-5) | 3.76 | 2.83 | 3.90 | 0.70 | 3.40 | 0.90 | 0.35 | 0.03-0.61 |

aGlobal scores were given on a five-point Likert scale (1 – 5), with a higher score indicating better MI skills

**Table S3. Quality of intervention implementation among individuals of participating organizations.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Components:** | **Measurements:** | **Police** |  |  |  | **Military** |  |  |  | **Hospital** |  |  |  |
|  |  | N | % | Mean | SD | N | % | Mean | SD | N | % | Mean | SD |
| Reach | Allocated to intervention groups after cardioscreening | 262 | 90 |  |  | 170 | 71 |  |  | 59 | 91 |  |  |
| Quantity | HRA fully completed | 152 | 89 |  |  | 229 | 87 |  |  | 51 | 86 |  |  |
|  | Newslettersread |  | 66a |  | 0.5 |  | 59a |  | 2.39 |  | 56a |  | 1.2 |
|  | *Extensive intervention group only* | 110 | 40 |  |  | 138 | 50 |  |  | 26 | 10 |  |  |
|  | MI-sessions:b | | | | | | | | | | | | |
|  | Total consultation length (mins) |  |  | 125.8a | 63.0 |  |  | 95.9a | 62.2 |  |  | 59.2a | 53.3 |
|  | Face-to-face |  |  | 2.7a | 1.28 |  |  | 2.6a | 1.8 |  |  | 1.4a | 1.0 |
|  | Telephone |  |  | 2.4a | 1.6 |  |  | 1.0a | 1.2 |  |  | 0.4a | 0.6 |
|  | At least 4 | 80a | 73 |  |  | 71a | 51 |  |  | 4a | 15 |  |  |
| Quality of MIb: MI fidelity | Behavior counts: | | | | | | | | | | | | |
|  | Open questions (%) |  |  | 50.3a | 9.5 |  |  | 31.1a | 9.0 |  |  | 31.0a | 2.5 |
|  | Reflections versus questions (%) |  | 117a |  | 60 |  | 94a |  | 41 |  | 218a |  | 0.4 |
|  | Complex reflections |  | 73a |  | 13.6 |  | 69a |  | 4.4 |  | 45a |  | 8.4 |
|  | MI adherent statements |  | 83a |  | 11.9 |  | 84a |  | 8.3 |  | 89a |  | 5.6 |
|  | Global scores: | | | | | | | | | | | | |
|  | Empathy (1-5) |  |  | 3.5a | 0.4 |  |  | 3.6a | 0.7 |  |  | 3.1a | 0.4 |
|  | Direction (1-5) |  |  | 4.6a | 0.5 |  |  | 4.2a | 0.5 |  |  | 4.3a | 0.2 |
|  | MI-spirit (1-5) |  |  | 3.8a | 0.5 |  |  | 3.4a | 0.5 |  |  | 3.4a | 0.3 |
|  | Mean global (1-5) |  |  | 3.9a | 0.4 |  |  | 3.6a | 0.4 |  |  | 3.4a | 0.2 |
| aSignificant differences between groups (p<0.05)  bExtensive intervention only, based on mean scores of both coders. | | | | | | | | | | | | | |