Oral health advice for people with serious mental illness (Protocol)

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[Intervention Protocol]

Oral health advice for people with serious mental illness

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To review the effects of oral health advice for people with serious mental illness.

BACKGROUND

Description of the condition

The definition of severe mental illness with the widest consensus is that of the National Institute of Mental Health (NIMH) (Schinnar 1990) and is based on diagnosis, duration and disability (NIMH 1987). People with serious mental illness have conditions such as schizophrenia or bipolar disorder, over a protracted period of time resulting in erosion of functioning in day to day life. A European survey put the total population-based annual prevalence of serious mental illness at approximately two per thousand (Ruggeri 2000). Evidence suggests that those with serious mental illness have a significantly increased chance of experiencing oral health problems than the general population Stiefel 1990; BSDH 2000). Oral health has not been seen as a priority in this group, although poor dental hygiene impacts on quality of life, affecting everyday functioning such as eating, comfort, appearance, social acceptance and self esteem, it is unlikely to be fatal (Cormac 1999). Poor oral health, however, has been linked to coronary heart disease (Montebugnoli 2004) and oral health is an important part of overall physical health. Many drugs routinely prescribed to those with serious mental illness lead to changes in physiology, some of which can be dangerous; the recognition of this has largely driven the monitoring of physical health symptoms in this client group. In particular, antipsychotics, antidepressants and mood stabilisers can cause xerostomia (dry mouth) which causes changes to the oral environment leading to periodontal disease (Friedlander 2002).

Description of the intervention

Oral health advice can take many forms depending on environmental and socioeconomic factors. Advice is the active provision of preventative information; it has an educative component and is delivered in a gentle non-patronising manner (Stott 1990). Therefore oral health advice could be defined as any verbal advice about oral health from a healthcare professional.

How the intervention might work

Advice from a healthcare professional can have a positive impact on behaviour (Kreuter 2000, Russell 1979). Advice may motivate people to seek further support and treatment (Sutherland 2003). Given the evidence of increased rates of potentially preventable health problems in people with serious mental illness (Cournos 2005, Dixon 1999, Robson 2007), and the suggestion from a systematic review (Bradshaw 2005) that methodologically robust, healthy living interventions give "promising outcomes" in people with schizophrenia, we believe that appropriate oral health advice could improve the quality and duration of life for sufferers of serious mental illness. Oral health advice from a healthcare professional may encourage those with serious mental illness to brush their teeth on a regular basis, have regular dental check-ups and seek help in a dental emergency.

Why it is important to do this review

Those with serious mental illness are less likely to seek medical advice and are more likely to be exposed to medications with potentially negative health consequences (Weinmann 2009). Those with serious mental illness also should stand to benefit from any oral health advice as there is evidence to suggest they have a greater risk of experiencing oral disease and have greater oral treatment needs than the general population (BSDH 2000). Oral health problems are not well recognised by mental health professionals and people with serious mental illnesses can experience barriers to treatment (Cormac 1999) including low tolerance to their lack of compliance with oral hygiene, and a lack of understanding of mental health problems from dental professionals (BSDH 2000). It is important to complete this review because medication used to treat mental illness may predispose to dental disease and this can have both local and systemic effects. We know of no systematic review of oral health advice for those with serious mental illness.

OBJECTIVES

To review the effects of oral health advice for people with serious mental illness.

METHODS

Criteria for considering studies for this review

Types of studies

We considered all relevant randomised controlled trials, and economic evaluations conducted alongside included randomised controlled trials. We excluded quasi-randomised studies, such as those allocating by using alternate days of the week. When we encountered trials described in some way as to suggest or imply that the study was randomised and where the demographic details of each group's participants were similar, we included them and a sensitivity analysis was undertaken to the presence or absence of these data.

Types of participants

We required that a majority of participants should be within the age range 18 to 65 years and suffering from severe mental illness preferably as defined by National Institute of Mental Health

(NIMH 1987) but in the absence of this, from diagnosed illnesses such as schizophrenia, schizophrenia-like disorders, bipolar disorder, or serious affective disorder. We did not consider substance abuse to be a severe mental disorder in its own right, however we did feel that studies should remain eligible if they dealt with people with dual diagnoses, that is those with severe mental illness plus substance abuse. We did not include studies focusing on dementia, personality disorder and mental retardation as they are not covered by our definition of severe mental illness.

Types of interventions

1. Oral health advice
We have found it difficult to find a useful definition of 'advice'. In the context of this review we define oral health advice as preventative information (Greenlund 2002) or counsel (OED) that enables the recipient to make the final decision about their oral health. It should have at least a suggestion of: i. an educative component; ii. a preventative aim; and iii. an ethos of self-empowerment. Advice may be directional but not paternalistic in its delivery. It is not a programmed or training approach, focusing on the acquisition of knowledge, skills, and competencies as a result of formal teaching sessions.
2. Standard care
Care in which oral health advice is not specifically emphasised above and beyond the care that would be expected for people suffering from severe mental illness.

Types of outcome measures

Primary outcomes

1. Oral health
1.1 Not owning a toothbrush
1.2 Not having seen a dentist in the past year
1.3 Not brushing teeth twice a day
1.4 Not flossing teeth twice a day
2. Quality of life
2.1 Loss of independence
2.2 Loss of Activities of Daily Living (ADL) skills
2.3 Chronic pain
2.4 Immobility
2.5 Loss of earnings
2.6 Loss of social status
2.7 Healthy days

Secondary outcomes

1. Adverse events
1.1 Number of participants with at least one adverse effect
1.2 Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count)
1.3 Average endpoint specific adverse effects score
1.4 Average change in specific adverse effects score
1.5 Death - natural or suicide
2. Service use
2.1 Hospital admission
2.2 Emergency medical/dental treatment
2.3 Use of emergency services
3. Financial dependency
3.1 Claiming unemployment benefit
3.2 Claiming financial assistance because of a physical disability
4. Social
4.1 Unemployment
4.2 Social isolation as a result of preventable incapacity
4.3 Increased burden to caregivers
5. Quality of life/satisfaction with treatment
5.1 No clinically important change in general quality of life
5.2 Average endpoint general quality of life score
5.3 Average change in general quality of life score
5.4 No clinically important change in general functioning
5.5 Average endpoint general functioning score
5.6 Average change in general functioning score
6. Economic
6.1 Increased costs of health care
6.2 Days off sick from work
6.3 Reduced contribution to society
6.4 Family claiming care allowance
7. Leaving the study early (any reason, adverse events, inefficacy of treatment)
8. Global state
8.1 No clinically important change in global state (as defined by individual studies)
8.2 Relapse (as defined by the individual studies)
9. Mental state (with particular reference to the positive and negative symptoms of schizophrenia)
9.1 No clinically important change in general mental state score
9.2 Average endpoint general mental score
9.3 Average change in general mental state score
9.4 No clinically important change in specific symptoms (positive symptoms of schizophrenia, negative symptoms of schizophrenia)
9.5 Average endpoint specific symptom score
9.6 Average change in specific symptom score
10. Dental state
10.1 Increased plaque index
10.2 Teeth lost due to decay
10.3 Increase in dental caries
10.4 Increase in periodontal disease
10.5 Increase in oral infections

Search methods for identification of studies

Electronic searches

Electronic searches Cochrane Schizophrenia Group Trials Register (October 2009)

The register was searched using the phrase:[(*physical* or *cardio* or *metabolic* or *weight* or *HIV* or *AIDS* or *Tobacc* or *Smok* or *sex* or *medical* or *dental* or *alcohol* or *oral* or *vision* or *sight*or *hearing* or *nutrition* or *advice* or *monitor* in title of REFERENCES) AND (*education* OR *health promot* OR *preventi* OR *motivate* or *advice* or *monitor* in interventions of STUDY)]

This register is compiled by systematic searches of major databases, hand searches and conference proceedings (see Group Module).

Searching other resources

1. Reference searching
We inspected the references of all identified studies for other relevant studies.
2. Personal contact
We contacted the first author of each included trial for information regarding unpublished studies, we also contacted the first author of each ongoing study and requested information about current progress.

Data collection and analysis

Selection of studies

Authors GT and AC screened the results of the electronic search. WK inspected a random sample of these abstracts, comprising 10% of the total. Where disagreement occurred we resolved this by discussion, and where there was still doubt, we acquired the full article for further inspection. We then requested the full articles of relevant reports for reassessment and carefully inspected them for a final decision on inclusion (see Criteria for considering studies for this review). In turn GT and AC inspected all full reports and independently decided whether they met inclusion criteria. We were not blinded to the names of the authors, institutions or journal of publication. Where difficulties or disputes arose, we asked another author for help and if it was impossible to decide, these studies were added to those awaiting assessment and the authors of the papers contacted for clarification.

Data extraction and management

1. Extraction
Authors GT and AC independently extracted data from included studies. Again, we discussed any disagreement, documented our decisions and, if necessary, we contacted the authors of studies for clarification. Whenever possible we only extracted data presented in graphs and figures, we only included data if two reviewers independently had the same result. We made attempts to contact authors through an open-ended request, in order to obtain any missing information or for clarification whenever necessary. Where possible, we extracted data relevant to each component centre of multi-centre studies separately.
2. Management
2.1 Forms
GT and AC extracted data onto standard, simple forms.
2.2 Data from multi-centre trials
Where possible the authors verified independently calculated centre data against original trial reports.
3. Scale-derived data
We included continuous data from rating scales only if:
a. the psychometric properties of the measuring instrument had been described in a peer-reviewed journal (Marshall 2000); and
b. the measuring instrument was not written or modified by one of the trialists for that particular trial; and
c. the measuring instrument is either i. a self-report or ii. completed by an independent rater or relative.
4. Endpoint versus change data
We preferred to use scale endpoint data, which typically cannot have negative values and is easier to interpret from a clinical point of view. Change data are often not ordinal and are very problematic to interpret. If endpoint data were unavailable, we used change data.
5. Skewed data
Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we aimed to apply the following standards to all data before inclusion: (a) standard deviations and means are reported in the paper or obtainable from the authors; (b) when a scale starts from the finite number zero, the standard deviation, when multiplied by two, is less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution, (Altman 1996); (c) if a scale starts from a positive value (such as PANSS which can have values from 30 to 210) the calculation described above will be modified to take the scale starting point into account. In these cases skew is present if 2SD>(S-S min), where S is the mean score and S min is the minimum score. Endpoint scores on scales often have a finite start and endpoint and these rules can be applied. When continuous data are presented on a scale which includes a possibility of negative values (such as change data), it is difficult to tell whether data are skewed or not. We entered skewed data from studies of less than 200 participants in additional tables rather than into an analysis. Skewed data pose less of a problem when looking at means if the sample size is large, and we entered skewed data from large sample sizes into syntheses.
6. Common measure
To facilitate comparison between trials, we intend to convert vari-

ables that can be reported in different metrics, such as days in hospital, (mean days per year, per week or per month) to a common metric (e.g. mean days per month).
7. Conversion of continuous to binary
Where possible, we made efforts to convert outcome measures to dichotomous data. This could be done by identifying cut-off points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It was generally assumed that if there had been a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (BPRS, Overall 1962) or the Positive and Negative Syndrome Scale (Kay 1986, Kay 1987), this could be considered as a clinically significant response (Leucht 2005, Leucht 2005a). If data based on these thresholds were not available, we used the primary cut-off presented by the original authors.
8. Direction of graphs
Where possible, we entered data in such a way that the area to the left of the line of no effect indicates a favourable outcome for oral health advice.
9. Summary of findings table
We anticipate including the following outcomes in a summary of finding table.
9.1 Oral health
-Not having seen a dentist in the past year
-Not brushing teeth twice a day
9.2.Quality of life
-Chronic pain
9.3 Adverse event
- Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects,
weight gain, effects on white blood cell count)
9.4 Service use
-Emergency medical/dental treatment
9.4 Leaving the study early
- Increased costs of health care
9.5 Dental state
- No clinically important change in plaque index

Assessment of risk of bias in included studies

Again working independently, GT and AC assessed risk of bias using the tool described in the Cochrane Collaboration Handbook (Higgins 2008). This tool encourages consideration of how the sequence was generated, how allocation was concealed, the integrity of blinding at outcome, the completeness of outcome data, selective reporting and other biases. We excluded studies where allocation was clearly not concealed. The risk of bias in each domain, and overall, are assessed and categorised into:
A. Low risk of bias: plausible bias unlikely to seriously alter the results (categorised as 'Yes' in Risk of Bias table)
B. High risk of bias: plausible bias that seriously weakens confidence in the results (categorised as 'No' in Risk of Bias table)
C. Unclear risk of bias: plausible bias that raises some doubt about the results (categorised as 'Unclear' in Risk of Bias table)
We did not include trials with high risk of bias (defined as at least 3 out of 5 domains categorised as 'No') in the meta-analysis. If the raters disagreed, the final rating was made by consensus with the involvement of another member of the review group. Where inadequate details of randomisation and other characteristics of trials are provided, we contacted the authors of the studies in order to obtain further information. Non-concurrence in quality assessment was reported.

Measures of treatment effect

1. Binary data
For binary outcomes we calculated a standard estimation of the random-effect risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive (Boissel 1999) than odds ratios and that odds ratios tend to be interpreted as RR by clinicians (Deeks 2000). Within the Summary of Findings table we assumed for calculation of the low risk groups that the lowest control risk applied to all data. We did the same for the assumption of the highest risk groups. We used the Summary of Findings table to calculate absolute risk reduction for primary outcomes.
2. Continuous data
2.1 Summary statistic
For continuous outcomes we estimated a random-effect mean difference (MD) between groups. We preferred not to calculate effect size measures (standardised mean difference - SMD). However, in the case of where scales were of such similarity to allow presuming there was a small difference in measurement, we calculated it and, whenever possible, we transformed the effect back to the units of one or more of the specific instruments.

Unit of analysis issues

1. Cluster trials
Studies increasingly employ 'cluster randomisation' (such as randomisation by clinician or practice) but analysis and pooling of clustered data poses problems. Firstly, authors often fail to account for intra class correlation in clustered studies, leading to a 'unit of analysis' error (Divine 1992) whereby p values are spuriously low, confidence intervals unduly narrow and statistical significance overestimated. This causes type I errors (Bland 1997, Gulliford 1999).
Where clustering is not accounted for in primary studies, we presented data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. In subsequent versions of this review we will seek to contact first authors of studies to obtain intra class correlation co-efficient of their clustered data and to adjust for this by using accepted methods (Gulliford 1999). Where clustering had been incorporated into the analysis of primary studies, we present these data as if from a non-cluster randomised study, but adjusted for the clustering effect.

We have sought statistical advice and have been advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the intra class correlation co-efficient (ICC) [Design effect = 1+(m-1)*ICC] (Donner 2002). If the ICC was not reported it was assumed to be 0.1 (Ukoumunne 1999).
If cluster studies have been appropriately analysed, taking into account intra class correlation co-efficient and relevant data documented in the report, synthesis with other studies would be possible using the generic inverse variance technique.
2. Cross-over trials
A major concern of cross-over trials is the carryover effect. This occurs if an effect (e.g. pharmacological, physiological or psychological) of the treatment in the first phase is carried over to the second phase. As a consequence, on entry to the second phase the participants can differ systematically from their initial state despite a wash-out phase. For the same reason cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). As both effects are very likely in severe mental illness, we only used data from the first phase of cross-over trials.
3. Studies with multiple treatment groups
Where a study involved more than two treatment arms, if relevant, we presented the additional treatment arms in comparisons. Where the additional treatment arms were not relevant, we did not reproduce these data.

Dealing with missing data

1. Overall loss of credibility
At some degree of loss of follow up data must lose credibility (Xia 2009). For any particular outcome should than 50% of data be unaccounted, we did not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study were lost, but the total loss was less than 50%, we marked such data with '*' to indicate that such a result may well be prone to bias.

2. Binary
In the case where attrition for a binary outcome is between 0 and 50% and where these data were not clearly described, we presented data on a 'once-randomised-always-analyse' basis (an intention to treat analysis). Those lost to follow up were all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death. A sensitivity analysis was undertaken testing how prone the primary outcomes were to change when 'completer' data only were compared to the intention to treat analysis using the above assumption.

3. Continuous
3.1 Attrition
In the case where attrition for a continuous outcome is between 0 and 50% and completer-only data were reported, we reproduced these.

3.2 Standard deviations
Where there are missing measures of variance for continuous data but exact standard error and confidence intervals are available for group means, and either 'p' value or 't' value are available for differences in mean, we calculated a standard deviation value according to the method described in Section 7.7.3 of the Cochrane Handbook (Higgins 2008). If standard deviations were not reported and could not be calculated from available data, we asked authors to supply the data. In the absence of data from authors, the mean standard deviation from other studies was used.

3.3 Last observation carried forward
We anticipated that in some studies the method of last observation carried forward (LOCF) would be employed within the study report. As with all methods of imputation to deal with missing data, LOCF introduces uncertainty about the reliability of the results. Therefore, where LOCF data has been used in the trial, if less than 50% of the data had been assumed, we reproduced these data and indicated that they are the product of LOCF assumptions.

Assessment of heterogeneity

1. Clinical heterogeneity
To judge clinical heterogeneity, we considered all included studies, initially without seeing comparison data. We simply inspected all studies for clearly outlying situations or people which we had not predicted would arise. Should such situations or participant groups arise these will be fully discussed.

2. Methodological heterogeneity
We considered all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We simply inspected all studies for clearly outlying methods which we had not predicted would arise. Should such methodological outliers arise these will be fully discussed.

3. Statistical
3.1 Visual inspection
We visually inspected graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I-squared statistic
Heterogeneity between studies was investigated by considering the I-squared method alongside the Chi^2 'p' value. The I^2 provides an estimate of the percentage of inconsistency thought to be due to chance (Higgins 2003). The importance of the observed value of I^2 depends on i. magnitude and direction of effects and ii. strength of evidence for heterogeneity (e.g. 'p' value from Chi^2 test, or a confidence interval for I^2). An I^2 estimate greater than or equal to 50% accompanied by a statistically significant Chi^2 statistic, was interpreted as evidence of substantial levels of heterogeneity (Section 9.5.2 - Higgins 2008) and reasons for heterogeneity were

explored. If the inconsistency was high and the clear reasons were found, we presented data separately.

Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results (Egger 1997). These are described in Section 10 of the Cochrane Handbook (Higgins 2008). We are aware that funnel plots may be useful in investigating reporting biases but are of limited power to detect small-study effects. We will not use funnel plots for outcomes where there were ten or fewer studies, or where all studies were of similar sizes. In other cases, where funnel plots are possible, we will seek statistical advice in their interpretation.

Data synthesis

Where possible we will employ a random-effect model for analyses. We understand that there is no closed argument for preference for use of fixed or random-effect models. The random-effect method incorporates an assumption that different studies are estimating different, yet related, intervention effects. According to our hypothesis of an existing variation across studies, to be explored further in the meta-regression analysis despite being cautious that that random-effects methods does put added weight onto the smaller of the studies - we favoured using random-effect model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses
We anticipate no sub-group analyses.

2. Investigation of heterogeneity
2.1 Unanticipated heterogeneity
Should unanticipated clinical or methodological heterogeneity be obvious we will simply state hypotheses regarding these for future reviews or versions of this review. We do not anticipate undertaking analyses relating to these.

2.2 Anticipated heterogeneity
We anticipate some heterogeneity for the primary outcomes and propose to summate all data but also present them separately.

Sensitivity analysis

1. Implication of randomisation
We aim to include trials in a sensitivity analysis if they are described in some way as to imply randomisation. For the primary outcomes we will include these studies and if there was no substantive difference when we added the implied randomised studies to those with better description of randomisation, we then employed all data from these studies.

2. Assumptions for lost binary data
Where assumptions have to be made regarding people lost to follow up (see Dealing with missing data) we compared the findings of the primary outcomes where we used our assumption and compared with completer data only. If there is a substantial difference, we reported results and discussed them but continued to employ our assumption.

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* *Indicates the major publication for the study*

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Waqqas Ahmad Khokhar - primary reviewer, protocol writing.

Mohammad Mubashar MI Ali - help with writing the protocol.

Hannah Jones - help with writing the protocol.

Andrew Clifton - help with writing the protocol.

Graeme Tosh - project initiation, help with writing the protocol.

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External sources

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