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Social skills programmes for schizophrenia

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Abstract

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

The primary objective is to investigate the effects of social skills training programmes, compared to standard care, for people with schizophrenia.

BACKGROUND

Description of the condition

Schizophrenia can occur as a single episode of illness. By far the greater proportion of sufferers, however, have remission and relapses; for up to 41% of those who develop schizophrenia it becomes a chronic and often disabling illness (Prudo 1987). Antipsychotic medications are commonly used for management of symptoms. However, the conclusions reached by meta-analytical methods are that treatment with antipsychotic medication 'should be combined and coordinated with other interventions involving the

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Muhammad Qutayba Almerie - helped write protocol.
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DECLARATIONS OF INTEREST
Nicola Maayan - currentlys work for Enhance Reviews Ltd, a company that carries out systematic reviews mostly for the public sector, they currently do not provide services for the pharmaceutical industry.

patient's family, and social psychological and psychotherapeutic support' (MSPI 1997). These treatments are subsumed under the general term 'rehabilitation'.

Preceding the movement of care into the community, the rehabilitation process was mostly provided by the large psychiatric hospitals in which sufferers often spent many years (Wing 1961, Wing 1970). This pattern of care has now changed (Hume 1995). During the 1980s many psychiatric hospitals were closed, community-based services were developed, and psychiatric units in general hospitals were established. Currently, few chronically mentally ill people spend longer than a few weeks per year in hospital. The rest of their care takes place in the community. Up to 75% of people with chronic schizophrenia are maintained in the community in the United Kingdom - chronic in this case is defined as lasting more than 2.5 years (Davies 1990). Relative to other chronic illnesses, the personal and economic costs of schizophrenia are considerable (Knapp 1994). It is therefore important to offer rehabilitation treatments that are both clinically effective and cost-effective.

Description of the intervention

As a part of the rehabilitation package for people with schizophrenia, social skills programmes (SSP) aim to utilise behaviour therapy principles and techniques for teaching individuals to communicate their emotions and requests, so they are more likely to achieve their goals and meet their needs for relationships and roles required for independent living and social competence (Kopelowicz 2006). SSP involves 'model learning' (role playing) which was introduced to improve general 'molecular' skills (eye contact, fluency of speech, gestures, etc) and 'molar' skills (managing negative affects, giving positive feedback, etc.) (Brenner 1994). A problem-solving model was later incorporated and rehabilitation topics that are particularly relevant for people with schizophrenia were introduced (Liberman 1993). The application of these modules appears far more effective than control conditions, particularly in terms of generalisation of skills and social adjustment (Marder 1996, Wallace 1998).

How the intervention might work

Learning-based procedures used in SSP include identifying the problems and setting the goals in collaboration with the client. Through role play or behavioural rehearsal, participants demonstrate the required skills and positive or corrective feedback is given to them accordingly. By social modelling and behavioural practice participants observe and repeat the skills until the communications reach a level of quality tantamount to success in the real-life situation. Homework assignments are then given to motivate participants to implement these communications in real-life situations.

Why it is important to do this review

This review focuses on social skills programmes, which are some of the most established psychosocial treatments for schizophrenia (Liberman 1986; Liberman 1986a) but vary in use across the world. Essentially social skills programmes are treatment strategies aimed at enhancing the social performance and reducing the distress and difficulty experienced by people with a diagnosis of schizophrenia. Few reviews exist (Kopelowicz 2006) and none are maintained.

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OBJECTIVES

The primary objective is to investigate the effects of social skills training programmes, compared to standard care, for people with schizophrenia.

METHODS

Criteria for considering studies for this review

Types of studies—All relevant randomised controlled trials. If a trial is described as 'double blind' but implies randomisation, we will include such trials in a sensitivity analysis. If their inclusion does not result in a substantive difference, they will remain in the analyses. If their inclusion does result in statistically significant differences, we will not add the data from these lower quality studies to the results of the better trials, but will present such data within a subcategory. We will exclude quasi-randomised studies, such as those allocating by alternate days of the week. Where people are given additional treatments within a social skills trial, we will only include data if the adjunct treatment is evenly distributed between groups and it is only the social skills programme that is randomised.

Types of participants—Adults, however defined, with schizophrenia or related disorders, including schizophreniform disorder, schizoaffective disorder and delusional disorder, again, by any means of diagnosis.

We are interested in making sure that information is as relevant to the current care of people with schizophrenia as possible so propose to clearly highlight the current clinical state (acute, early post-acute, partial remission, remission) as well as the stage (prodromal, first episode, early illness, persistent) and as to whether the studies primarily focused on people with particular problems (for example, negative symptoms, treatment-resistant illnesses).

Types of interventions

1. Social skills training programmes: Defined as any structured psychosocial intervention, whether group or individual, aimed at enhancing the social performance and reducing the distress and difficulty in social situations. The key components are; i. a careful behavioural based assessment of a range of social and interpersonal skills; ii. An importance placed on both verbal and non-verbal communication; as well as the individual's ability to; i. perceive and process relevant social cues; and ii. to respond to and provide appropriate social reinforcement. This approach has the goal of building up individual behavioural elements into complex behaviours. The aim is to develop more effective social communication. There is considerable emphasis not just on clinic based interventions (including modelling, role-play and social reinforcement) but also the setting of homework tasks and the applicability of the treatment.

Programmes where social skills training are a component part of a more complex rehabilitation intervention are excluded, as are token economies, life skills programmes and other similar milieu based interventions which may include an element of social skills training in a broader programme.

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Programmes of five sessions and less are considered as 'brief ', and six or more as 'long'. Place of residence is defined as either 'hospital' or 'community' for the purposes of this review. For example, if people are in hospital at time of attending a day-hospital based programme they are considered to be receiving 'hospital-based' care. If, on the other hand, they attend the day hospital from home then they are considered to be receiving' community-based' care. Trained staff are those personnel who hold a professionally recognised health care qualification.

2. The control treatment: Defined as standard care without a dedicated programme of the type described above.

Types of outcome measures—All outcomes will be divided into short term (less than 6 months), medium term (7-12 months) and long term (over 1 year).

Primary outcomes

1. Social functioning

2. Clinical response

3. Service utilisation outcomes: Hospital admission

Secondary outcomes

1. Death, suicide or natural causes

2. Leaving the study early

3. Social functioning

4. Clinical response

5. Adverse effects

6. Service utilisation outcomes

7. Economic outcomes

8. Quality of life / satisfaction with care for either recipients of care or carer/s

Search methods for identification of studies

Electronic searches—The Cochrane Schizophrenia Group Trials Register will be searched using the phrase: [((*social* OR *personal*) AND (*skill* OR *program* OR *training*)) in title, abstract and indexing terms fields in REFERENCE and (*social skill* OR *social support* OR *sociotherapy* OR *socioenvironmental* OR *interpersonal*) in 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 will inspect references of all identified studies for further relevant studies.

2. Personal contact: We will contact the first author of each included study for information regarding unpublished trials.

Data collection and analysis

Selection of studies—MOA and MS will independently inspect citations from the searches and identify relevant abstracts. A random 20% sample will be independently re-inspected by MQA to ensure reliability. Where disputes arise, the full report will be acquired for more detailed scrutiny. Full reports of the abstracts meeting the review criteria will be obtained and inspected by MOA and MS. Again, a random 20% of reports will be re-inspected by MQA in order to ensure reliable selection. Where it is not possible to resolve disagreement by discussion, we will attempt to contact the authors of the study for clarification.

Data extraction and management

1. Extraction—Reviewer MOA will extract data from all included studies. In addition, to ensure reliability, NM will independently extract data from a random sample of these studies, comprising 10% of the total. Again, any disagreement will be discussed, decisions documented and, if necessary, authors of studies will be contacted for clarification. With remaining problems NM will help clarify issues and these final decisions will be documented. Data presented only in graphs and figures will be extracted whenever possible, but included only if two reviewers independently have the same result. Attempts will be made to contact authors through an open-ended request in order to obtain missing information or for clarification whenever necessary. If studies are multi-centre, where possible, we will extract data relevant to each component centre separately.

2. Management

2.1 Forms: Data will be extracted onto standard, simple forms.

2.2 Scale-derived data: We will include continuous data from rating scales only if:

- **a.** the psychometric properties of the measuring instrument have been described in a peer-reviewed journal (Marshall 2000); and
- **b.** the measuring instrument has not been written or modified by one of the trialists for that particular trial.

Ideally the measuring instrument should either be i. a self-report or ii. completed by an independent rater or relative (not the therapist). We realise that this is not often reported clearly, in Description of studies we will note if this is the case or not.

2.3 Endpoint versus change data: There are advantages of both endpoint and change data. Change data can remove a component of between-person variability from the analysis. On the other hand calculation of change needs two assessments (baseline and endpoint) which can be difficult in unstable and difficult to measure conditions such as schizophrenia. We have decided to primarily use endpoint data, and only use change data if the former are not available. Endpoint and change data will be combined in the analysis as we will use mean differences (MD) rather than standardised mean differences throughout (Higgins 2009, Chapter 9.4.5.2).

2.4 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 aim 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 started from a positive value (such as PANSS which can have values from 30 to 210) the calculation described above was 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 end point and these rules can be applied. When continuous data are presented on a scale that includes a possibility of negative values (such as change data), it is difficult to tell whether data are skewed or not. Skewed data from studies of less than 200 participants will be entered 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 will be entered into syntheses.

2.5 Common measure: To facilitate comparison between trials, we intend to convert variables 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).

2.6 Conversion of continuous to binary: Where possible, efforts will be made to convert outcome measures to dichotomous data. This can be done by identifying cut-off points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It is generally assumed that if there is 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 (PANSS, Kay 1986), this could be considered as a clinically significant response (Leucht 2005, Leucht 2005a). If data based on these thresholds are not available, we will use the primary cut-off presented by the original authors.

2.7 Direction of graphs: Where possible, we will enter data in such a way that the area to the left of the line of no effect indicates a favourable outcome for social skills training. Where keeping to this makes it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'Not improved') we will report data where the left of the line indicates an unfavourable outcome. This will be noted in the relevant graphs.

2.8 Summary of findings table: We will use the GRADE approach to interpret findings (Schünemann 2008) and use GRADE profiler (GRADE 2004) to import data from RevMan 5 (Review Manager 2008) to create 'Summary of findings' tables. These tables provide outcome-specific information concerning the overall quality of evidence from each included study in the comparison, the magnitude of effect of the interventions examined, and the sum of available data on all outcomes will be rated as important to patient-care and decision making. We will select the following main outcomes for inclusion in the summary of findings table:

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1. Social functioning - Clinically significant response on social skills - as defined by each of the studies

2. Clinical response

- Clinically significant response in global state - as defined by each of the studies
- Healthy days

3. Service utilisation outcomes

- Hospital admission
- Days in hospital

4. Adverse effect - Any important adverse event

5. Quality of life - Improved to an important extent

Assessment of risk of bias in included studies

Again NM and MOA will work independently to assess risk of bias by using criteria described in the Cochrane Collaboration Handbook (Higgins 2009) to assess trial quality. This set of criteria is based on evidence of associations between overestimate of effect and high risk of bias of the article such as sequence generation, allocation concealment, blinding, incomplete outcome data and selective reporting.

If the raters disagree, the final rating will be 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, authors of the studies will be contacted in order to obtain further information. Non-concurrence in quality assessment will be reported, but if disputes arise as to which category a trial is to be allocated, again, resolution will be made by discussion.

The level of risk of bias will be noted in both the text of the review and in the Summary of findings table 1.

Measures of treatment effect

1. Binary data—For binary outcomes we will calculate a standard estimation of the 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). For statistically significant results we had planned to calculate the number needed to treat to provide benefit /to induce harm statistic (NNTB/H), and its 95% confidence interval (CI) using Visual Rx (http://www.nntonline.net/) taking account of the event rate in the control group. This, however, has been superseded by Summary of findings table 1 and calculations therein.

2. Continuous data—For continuous outcomes will estimate mean difference (MD) between groups. We prefer not to calculate effect size measures (standardised mean difference SMD). However, if scales of very considerable similarity are used, we would have presumed there was a small difference in measurement, and we would have calculated

effect size and 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 will present 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 coefficients for their clustered data and to adjust for this by using accepted methods (Gulliford 1999). Where clustering has been incorporated into the analysis of primary studies, we will present these data as if from a non-cluster randomised study, but adjust 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 coefficient (ICC) [Design effect = 1+(m-1)*ICC] (Donner 2002). If the ICC is not reported it will be assumed to be 0.1 (Ukoumunne 1999).

If cluster studies have been appropriately analysed taking into account intra-class correlation coefficients and relevant data documented in the report, synthesis with other studies would have been possible using the generic inverse variance technique.

2. Cross-over trials—A major concern of cross-over trials is the carry-over effect. It 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 will only use data of the first phase of cross-over studies.

3. Studies with multiple treatment groups—Where a study involves more than two treatment arms, if relevant, the additional treatment arms will be presented in comparisons. If data are binary these will be simply added and combined within the two-by-two table. If data are continuous we will combine data following the formula in section 7.7.3.8 (Combining groups) of the Cochrane Handbook. Where the additional treatment arms are not relevant, these data will not be reproduced.

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Dealing with missing data

1. Overall loss of credibility—At some degree of loss of follow-up data must lose credibility (Xia 2009). We choose that, for any particular outcome, should more than 50% of data be unaccounted for, we will not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study are lost, but the total loss was less than 50%, we will mark 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 are not clearly described, data will be presented on a ’once-randomised-always-analyse’ basis (an intention to treat analysis). Those leaving the study early are all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death and adverse effects. For these outcomes the rate of those who stayed in the study - in that particular arm of the trial - will be used for those who did not. A sensitivity analysis will be undertaken testing how prone the primary outcomes are to change when ’completer’ data only are compared to the intention to treat analysis using the above assumptions.

3. Continuous

3.1 Attrition: In the case where attrition for a continuous outcome is between 0 and 50% and completer-only data will be reported, we will reproduce these.

3.2 Standard deviations: If standard deviations are not reported, we will first try to obtain the missing values from the authors. If not available, where there are missing measures of variance for continuous data, but an exact standard error and confidence intervals available for group means, and either ’p’ value or ’t’ value available for differences in mean, we can calculate them according to the rules described in the Cochrane handbook (Higgins 2009): When only the standard error (SE) is reported, standard deviations (SDs) are calculated by the formula SD = SE * square root (n). Chapters 7.7.3 and 16.1.3 of the Cochrane handbook (Higgins 2009) present detailed formula for estimating SDs from p-values, t or F values, confidence intervals, ranges or other statistics. If these formula do not apply, we will calculate the SDs according to a validated imputation method which is based on the SDs of the other included studies (Furukawa 2006). Although some of these imputation strategies can introduce error, the alternative would be to exclude a given study’s outcome and thus to lose information. We nevertheless will examine the validity of the imputations in a sensitivity analysis excluding imputed values.

3.3 Last observation carried forward: We anticipate that in some studies the method of last observation carried forward (LOCF) will 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 (Leucht 2007). Therefore, where LOCF data have been used in the trial, if less than 50% of the data have been assumed, we will reproduce these data and indicate that they are the product of LOCF assumptions.

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Assessment of heterogeneity

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

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

3. Statistical heterogeneity

3.1 Visual inspection: We will visually inspect graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I^2 statistic: Heterogeneity between studies will be investigated by considering the I^2 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). I^2 estimate greater than or equal to around 50% accompanied by a statistically significant Chi^2 statistic, will be interpreted as evidence of substantial levels of heterogeneity (Section 9.5.2 - Higgins 2009). When substantial levels of heterogeneity are found in the primary outcome, we will explore reasons for heterogeneity (Subgroup analysis and investigation of heterogeneity).

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 for Systematic Reviews of Interventions (Higgins 2009). 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 are ten or fewer studies, or where all studies are of similar sizes. In other cases, where funnel plots are possible, we will seek statistical advice in their interpretation.

Data synthesis

We understand that there is no closed argument for preference for use of fixed or random-effects models. The random-effects method incorporates an assumption that the different studies are estimating different, yet related, intervention effects. This often seems to be true to us and the random-effects model takes into account differences between studies even if there is no statistically significant heterogeneity. There is, however, a disadvantage to the random effects model. It puts added weight onto small studies which often are the most biased ones. Depending on the direction of effect these studies can either inflate or deflate

the effect size. Therefore, we choose the random effects model for all analyses. The reader is, however, able to choose to inspect the data using the fixed model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses - only primary outcomes

1.1 Brief versus long: We anticipate sub-group analyses investigating 'brief social skills programmes' and 'longer' programmes (for the purposes of this review, programmes of five sessions and less will be considered as 'brief', and six or more, as 'long').

1.2 Clinical state, stage or problem: We propose to undertake this review and provide an overview of the effects of social skills training for people with schizophrenia in general. In addition, however, we will try to report data on subgroups of people in the same clinical state, stage and with similar problems.

2. Investigation of heterogeneity—If inconsistency is high, this will be reported. First we will investigate whether data has been entered correctly. Second, if data is correct, the graph will be visually inspected and studies outside of the company of the rest will be successively removed to see if heterogeneity is restored. For this review we decided that should this occur with data contributing to the summary finding of no more than around 10% of the total weighting, data will be presented. If not, data are not pooled and issues will be discussed. We know of no supporting research for this 10% cut off but are investigating use of prediction intervals as an alternative to this unsatisfactory state.

When unanticipated clinical or methodological heterogeneity are 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.

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 is no substantive difference when the implied randomised studies are added to those with better description of randomisation, then all data will be employed 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 will compare the findings of the primary outcomes when we use our assumption compared with completer data only. If there is a substantial difference, we will report results and discuss them but continue to employ our assumption.

Where assumptions have to be made regarding missing SDs data (see Dealing with missing data), we will compare the findings on primary outcomes when we use our assumption compared with complete data only. A sensitivity analysis will be undertaken testing how prone results are to change when 'completer' data only are compared to the imputed data

using the above assumption. If there is a substantial difference, we will report results and discuss them but continue to employ our assumption.

3. Risk of bias—We will analyse the effects of excluding trials that are judged to be at high risk of bias across one or more of the domains of randomisation (implied as randomised with no further details available) allocation concealment, blinding and outcome reporting for the meta-analysis of the primary outcome. If the exclusion of trials at high risk of bias does not substantially alter the direction of effect or the precision of the effect estimates, then data from these trials will be included in the analysis

4. Imputed values—We will also undertake a sensitivity analysis to assess the effects of including data from trials where we used imputed values for ICC in calculating the design effect in cluster randomised trials.

If substantial differences are noted in the direction or precision of effect estimates in any of the sensitivity analyses listed above, we will not pool data from the excluded trials with the other trials contributing to the outcome, but will present them separately

5. Fixed and random effects—All data will be synthesised using a random-effects model, however, we will also synthesise data for the primary outcome using a fixed-effects model to evaluate whether the greater weights assigned to larger trials with greater event rates, altered the significance of the results compared to the more evenly distributed weights in the random-effects model.

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SOURCES OF SUPPORT

Internal sources

- Faculty of Medicine, Damascus University, Syrian Arab Republic.

External sources

- No sources of support supplied

WHAT'S NEW

Date	Event	Description
5 February 2014	Amended	Author correction to the byline.

HISTORY

Protocol first published: Issue 2, 2011

Date	Event	Description
18 January 2012	Amended	Contact details updated.

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