Appendix B: Data Extraction Form

DATA EXTRACTION FORM

Date: _____
Trial ID: _____

1. Bibliographical details

First Author _____ Publication year _____

2. Details of study

General details

Country _____ recruitment period _____ Number of groups: _____

Inclusion criteria: _____

Exclusion criteria: _____
_____

3. No of participants

	OVERALL	Control group	Intervention group 1	Intervention group 2
Participation rate (% of those contacted recruited):				
Numbers **randomized**				
Cross-overs		C→I	I→C	
Numbers **completed** study (time point=)				
Numbers **completed** study (time point=)				
Numbers **used in analyses** (time point=)				
Numbers **used in analyses** (time point=)				
Post randomisation drop-outs				
Post randomisation exclusions				
Attrition rate (% of those randomised completing study)				

Reasons for attrition explicitly reported? □ YES □ NO, give details:

Was sample size large enough to detect a meaningful difference if it had existed? □ YES □ NO □ can't tell

Explain:

4. Participant characteristics at baseline

Age (mean, SD)				
Gender	___M ___F	___M ___F	___M ___F	___M ___F
Diabetes duration in years (mean, SD)				
Socio-economic status reported? Yes No give details: _____				
Ethnicity reported? Yes No				
BMI (mean, SD)				
INSULIN dose (u/kg/day) or other info				

- **Were the groups similar at baseline in all important characteristics**? □ YES   □ NO □ can't tell
- **If groups not similar at baseline, was this adjusted for in the analyses**?   □ YES   □ NO □ can't tell

5. Intervention

Type: □ **educational**
□ **Supportive Therapy** (incl. motivational interviewing, text messaging, solution focused therapy)
□ **CBT Therapy** (incl. goal setting, activity scheduling, problem solving, stress management)
□ **Family Therapy**   □ **Other** (eclectic approaches, training practitioners)

Nature (tick as many as apply):

□ Skills-training (e.g. insulin pump) □ Diet-related □ Exercise-related □ Family-related □ support
□ Stress reduction □ problem-solving □ goal-setting □ shared agenda □ solution-focused
□ Motivational/patient empowerment □ other (specify) _____

Explicit statement of theoretical base? □ NO □ YES specify: _____

Aim of intervention: _____

Overview of intervention: _____

_____

_____

Co-intervention: _____

Was the intervention sufficiently **well described to be replicated** in practice? □ Yes □ No □ Unclear

Was the intervention developed from a **pilot study**? □ Yes □ No □ Unclear

Was intervention delivery **standardised**? □ Yes □ No □ Unclear

Reference to where the **full trial protocol** can be accessed? □ Yes □ No □ Unclear

Interventionist(s)

□ Doctor □ Psychologist □ Nurse □ Nutritionist/dietician □ MDT member □ not clear □ other
Was the interventionist(s) **blinded**? □ YES   □ NO □ not stated

Setting

☐ Diabetes clinic ☐ Hospital (inpatient) ☐ home ☐ other community setting (_____) ☐ Not stated

Mode of delivery (tick as many as apply)

☐ Lecture ☐ Interactive discussion/interview ☐ Video ☐ Printed information/leaflet ☐ Computer
☐ Not clear ☐ other (specify) _____

Delivery of intervention

☐ Child ☐ parent ☐ Family or family group ☐ clinician ☐ other (_____) ☐ Not stated

Time spent

Duration of intervention _____ Time spent on each session _____ total No of sessions _____

Fidelity

Was the intervention sessions **delivered as planned** (e.g. consistent with protocol)? ☐ YES ☐ NO ☐ can't tell
Evidence for **training of interventionist(s)**? ☐ YES ☐ NO
How adherence to the protocol was **assessed/monitored**? _____

Reach

How many participants attended the sessions? _____

Was it sufficient to demonstrate the effect of the intervention? ☐ NO ☐ YES ☐ can't tell

6. Control & Maintenance

Type of care received in controls: _____

Advice for insulin/diet/exercise in both groups: _____ **Aside from the**

intervention, were both groups treated equally? ☐ YES ☐ NO ☐ can't tell

7. Design

☐ single center ☐ multi-center (specify) _____

Method of randomisation: _____

Unit of randomisation: ☐ individual ☐ cluster (specify: _____)

Type of randomisation: ☐ simple ☐ block (n= ____) ☐ minimisation ☐ stratified (by: _____)

Analysis:

☐ <u>Intention-to-treat</u>: *Patients are analysed with the group to which they were randomised regardless of the intervention they actually received. The outcome should be measured in all the patients (or imputed e.g. multiple imputation) and all the randomised participants should be included in the analysis.*
☐ <u>Available case analysis</u>: *Patients are analysed with the group to which they were randomised (ITT principle) **but** only patients in whom the outcomes can be measured are included*
☐ <u>Per-protocol</u>: *Patients who did **not receive** the intervention and who **crossed-over** to the other group are **excluded***
☐ <u>Treatment received analysis</u>: *patients are analysed according to the treatment that they received irrespective of the group to which they were allocated*
☐ <u>Unclear</u>

Different endpoints/outcomes with different analysis? specify_____

8. Applicability

Have important populations been excluded from the study? *(consider disadvantaged populations, and possible differences in the intervention effect)*

☐ Yes ☐ No ☐ Unclear

9. Assessments (specify whether from **start** or **end** of intervention)

☐ Baseline ☐ 6 months ☐ 1 year ☐ > 1 year (specify) _____

Primary outcome(s): _____

Secondary outcomes(s): _____

Were any adverse outcomes measured? □ YES   □ NO, explain: _____

Were appropriate statistical tests used to compare the groups? (When applicable, was clustering adequately addressed in

the analyses?)   □ YES   □ NO □ can't tell

Outcome 1

Outcome name	
Time points measured	
Outcome definition	
Person measuring/reporting	
Unit of measurement *(if relevant)*	
Scales: upper and lower limits *(indicate whether high or low score is good)*	
Is outcome/tool validated?	☐ ☐ ☐ Yes No Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	
Power	
Notes:	

Outcome 2

Outcome name	
Time points measured	
Outcome definition	
Person measuring/reporting	
Unit of measurement *(if relevant)*	
Scales: upper and lower limits *(indicate whether high or low score is good)*	
Is outcome/tool validated?	☐ ☐ ☐ Yes No Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	

Power	
Notes:	

Outcome 3

Outcome name	
Time points measured	
Outcome definition	
Person measuring/reporting	
Unit of measurement *(if relevant)*	
Scales: upper and lower limits *(indicate whether high or low score is good)*	
Is outcome/tool validated?	☐ ☐ ☐ Yes　No　Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	
Power	
Notes:	

Outcome 4

Outcome name	
Time points measured	
Outcome definition	
Person measuring/reporting	
Unit of measurement *(if relevant)*	
Scales: upper and lower limits *(indicate whether high or low score is good)*	

Is outcome/tool validated?	☐ ☐ ☐ Yes No Unclear	
Imputation of missing data *(e.g. assumptions made for ITT* *analysis)*		
Power		
Notes:		

Outcome 5

Outcome name	
Time points measured	
Outcome definition	
Person measuring/reporting	
Unit of measurement *(if relevant)*	
Scales: upper and lower limits *(indicate whether high or low* *score is good)*	

Is outcome/tool validated?	☐ ☐ ☐ Yes No Unclear	
Imputation of missing data *(e.g. assumptions made for ITT* *analysis)*		
Power		
Notes:		

Outcome 6

Outcome name	
Time points measured	

Outcome definition	
Person measuring/reporting	
Unit of measurement *(if relevant)*	
Scales: upper and lower limits *(indicate whether high or low* *score is good)*	
Is outcome/tool validated?	☐ ☐ ☐ Yes No Unclear
Imputation of missing data *(e.g. assumptions made for ITT* *analysis)*	
Power	
Notes:	

CONTINUOUS OUTCOMES

OUTCOME 1	Time	Baseline (mean and SD)	Post-intervention (mean and SD)	Change from baseline (mean and SD)	Other statistics
IG-1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 2	Time	Baseline (mean and SD)	Post-intervention (mean and SD)	Change from baseline (mean and SD)	Other statistics
IG- 1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 3	Time	Baseline (mean and SD)	Post-intervention (mean and SD)	Change from baseline (mean and SD)	Other statistics
IG- 1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 4	Time	Baseline (mean and SD)	Post-intervention (mean and SD)	Change from baseline (mean and SD)	Other statistics
IG- 1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 5	Time	Baseline (mean and SD)	Post-intervention (mean and SD)	Change from baseline (mean and SD)	Other statistics
IG- 1 (n=)					
IG -2 (n=)					

CG (n=)					

OUTCOME 6	**Time**	**Baseline** **(mean and SD)**	**Post-intervention (mean and SD)**	**Change from baseline (mean and SD)**	**Other statistics**
IG-1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 7	**Time**	**Baseline** **(mean and SD)**	**Post-intervention (mean and SD)**	**Change from baseline (mean and SD)**	**Other statistics**
IG- 1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 8	**Time**	**Baseline** **(mean and SD)**	**Post-intervention (mean and SD)**	**Change from baseline (mean and SD)**	**Other statistics**
IG- 1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 9	**Time**	**Baseline** **(mean and SD)**	**Post-intervention (mean and SD)**	**Change from baseline (mean and SD)**	**Other statistics**
IG- 1 (n=)					
IG -2 (n=)					
CG (n=)					

OUTCOME 10	**Time**	**Baseline** **(mean and SD)**	**Post-intervention (mean and SD)**	**Change from baseline (mean and SD)**	**Other statistics**
IG- 1 (n=)					

IG -2 (n=)					
CG (n=)					

BINARY OUTCOMES

OUTCOME 1	Time	Total number of participants	No of events
IG-1			
IG -2			
CG			
OUTCOME 2	Time	Total number of participants	No of events
IG-1			
IG -2			
CG			
OUTCOME 3	Time	Total number of participants	No of events
IG-1			
IG -2			
CG			
OUTCOME 4	Time	Total number of participants	No of events
IG-1			
IG -2			
CG			

Cochrane Collaboration's tool for assessing risk of bias

Domain	Risk of bias Low risk / High risk / Unclear			Support for judgement	Location in text *(pg & ¶/fig/table)*
Random sequence generation *(selection bias)*	☐	☐	☐		
Allocation concealment *(selection bias)*	☐	☐	☐		
Blinding of outcome assessment *(detection bias)*	☐	☐	☐	**Outcome group:** ☐ This information was not available ☐ Lack of blinding will not result in bias for this outcome	
(if required)	☐	☐	☐	**Outcome group:**	
Incomplete outcome data *(attrition bias)*	☐	☐	☐	**Outcome group:** ☐ There were no post-randomisation drop-outs ☐ There were post-randomisation drop-outs ☐ This information was not available	
Incomplete outcome data *(attrition bias)*	☐	☐	☐	**Outcome group:** ☐ There were no post-randomisation drop-outs ☐ There were post-randomisation drop-outs ☐ This information was not available	
Selective outcome reporting? *(reporting bias)*	☐	☐	☐	☐ All important outcomes were reported. ☐ Some important outcomes which will generally be assessed were not reported	
Other bias	☐	☐	☐		
Notes:					