CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Informed Consent Forms

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Informed consent Form – Patient participant

CARiAD Informed Consent Form - Patient participant

CARiAD – Carer Administration of as-needed sub-cutaneous medication for breakthrough symptoms in home-based dying patients

Participant Identification Number: | | | | |

Please initial box

1. I confirm that I have read, or have had read to me, the information sheet (v3 June 2018) for the CARiAD study and understand what is involved. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that I will be assigned to the new care or usual care group at random and that if I am in the usual care group the person caring for me will not be given the training required to administer as-needed sub-cutaneous medication and I will receive care as usual. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without the medical care or legal rights of myself or the person caring for me being affected. If I withdraw from the study the researchers will use the information I have provided up until that point, unless I indicate that I do not want them to. ☐

4. I understand that my medical notes and data collected during the study will be looked at by individuals involved in the trial and may be accessed by regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research. I understand that this data will be treated in the strictest confidence and give permission for these individuals to have access to this data. ☐

5. I agree to my General Practitioner and other members of my healthcare team being informed of my participation in the study. ☐

6. I understand that if I lose mental capacity, including the ability to communicate my wishes, then a consultee will be asked to advise on whether I should continue in the study. ☐

7. I understand that if the researchers have any serious concerns about my health, safety or well-being, they have a duty to inform my GP or another appropriate professional. ☐

8. I agree to take part in this study. ☐

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Consultee Declaration Form

CARiAD Consultee Declaration Form

CARiAD – Carer Administration of as-needed sub-cutaneous medication for breakthrough symptoms in home-based dying patients

Participant Identification Number: | | | | |

Please initial box

1. I _____ , have been consulted about _____'s participation in the CARiAD study. I have read the information sheet dated _____ (v3 June 2018) and understand what is involved. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that the person will be assigned to the new care or usual care group at random and that only carers in the intervention group will be given the training required to administer as-needed sub-cutaneous medication. ☐

3. I understand that I can request the person is withdrawn from the study at any time without giving any reason and without the medical care or legal rights of myself or the person being affected. If I request for the person to be withdrawn from the study the researchers will use the information provided up until that point, unless I indicate that I do not want them to. ☐

4. I understand that relevant sections of the person's medical notes and data collected during the study will be looked at by individuals involved in the trial and may be accessed by regulatory authorities or the NHS Trust, where it is relevant to their taking part in this research. I understand that this data will be treated in the strictest confidence and give permission for these individuals to have access to this data. ☐

5. I agree to the person's General Practitioner and other members of their healthcare team being informed of their participation in the study. ☐

6. In my opinion, the person would have no objection to taking part in the study. ☐

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

7. Please could you let us know whether you would like to receive a summary of the findings at the end of the study? This information will not be available until all data has been collected and analysed (a period of up to eighteen months).

Yes - I would like to receive information once the research is complete (please provide contact details on the attached form). ☐

No - I do **not** want to receive a summary of the findings at the end of the study. ☐

Name of Consultee	Date	Signature
Relationship to participant:		
Name of Person undertaking consultation	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

CARiAD Carer contact details

Please provide contact details below if you would like to receive a summary of findings at the end of the study.

Name	
Postal address	
Email address	

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Informed Consent Form – Carer participant (pilot trial)

CARiAD Informed Consent Form - Carer participant

CARiAD – Carer Administration of as-needed sub-cutaneous medication for breakthrough symptoms in home-based dying patients

Participant Identification Number: | | | | |

Please initial box

1. I confirm that I have read, or have had read to me, the information sheet (v3 June 2018) for the CARiAD study and understand what is involved. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that I will be assigned to the new care or usual care group at random and that if I am in the usual care group I will not be given the training required to administer as-needed sub-cutaneous medication to the person I am caring for and they will receive care as usual. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without the medical care or legal rights of myself or the person I am caring for being affected. If I withdraw from the study the researchers will use the information I have provided up until that point, unless I indicate that I do not want them to. ☐

4. I understand that data collected during the study will be looked at by individuals involved in the trial and may be accessed by regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research. I understand that this data will be treated in the strictest confidence and give permission for these individuals to have access to this data. ☐

5. I understand that if the researchers have any serious concerns about my health, safety or well-being, they have a duty to inform my GP or another appropriate professional. ☐

6. I agree to take part in this study. ☐

CONTINUED OVERLEAF

Please could you let us know whether you would like to receive a summary of the findings at the end of the study? This information will not be available until all data has been collected and analysed (a period of up to eighteen months).

Yes - I would like to receive information once the research is complete (please provide contact details on the attached form). ☐

No - I do **not** want to receive a summary of the findings at the end of the study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

CARiAD Carer contact details

Please provide contact details below if you would like to receive a summary of findings at the end of the study.

Name	
Postal address	
Email address	

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Informed Consent Form – Carer participant

(embedded qualitative study)

CARiAD Informed Consent Form - Carer participant

CARiAD – Carer Administration of as-needed sub-cutaneous medication for breakthrough symptoms in homebased dying patients

Participant Identification Number: | | | | |

Please initial box

1. I confirm that I have read, or have had read to me, the information sheet (v2 June 2018) for the CARiAD study interviews and understand what is involved. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. If I withdraw from the study the researchers will use the information I have provided up until that point, unless I indicate that I do not want them to. ☐

3. I agree to the interview being audio recorded and transcribed. ☐

4. I agree to the use of anonymised quotes in presentations and publications. ☐

5. I understand that if the researchers have any serious concerns about my health, safety or well-being, they have a duty to inform my GP or another appropriate professional ☐

6. I agree to take part in the study. ☐

Please could you let us know whether you would like to receive a summary of the findings at the end of the study? This information will not be available until all data has been collected and analysed (a period of up to eighteen months).

Yes - I would like to receive information once the research is complete (please provide contact details on the attached form). ☐

No - I do **not** want to receive a summary of the findings at the end of the study. ☐

Name of Participant	Date	Signature
Name of person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file;

CARiAD Carer contact details

Please provide contact details below if you would like to receive a summary of findings at the end of the study.

Name	
Postal address	
Email address	