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

Participant Information Sheets

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

Information sheet for patients

CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home.
Information sheet for patients

We would like to invite you and the family member/friend who is involved in your care to take part in the CARiAD project. The project is about how we might teach carers who are looking after a very ill person at home to give extra doses of medication under the skin to the person they are caring for when they experience breakthrough symptoms. The care you already receive at home would be just the same, and this would be something extra that the person helping with your care could do. Your team of nurses and doctors have chosen you as someone who might want to take part in this trial because you are seriously ill and want to spend your last days of life at home with the help of a family member or friend who is acting as your carer.

What is the CARiAD project and why is it needed?

People who are seriously ill and nearing the end of their life may want to be cared for in their own homes. As their illness gets worse they may find it difficult to take medicines by mouth – either because they are experiencing nausea and vomiting or because they are becoming too weak to swallow. In the UK, when this happens, it is usual practice for a **cannula** to be put in – this is a small plastic tube placed under the skin. Once it is in place it can be used to give the person medication under the skin **without** using needles – this is sometimes called a **sub-cutaneous injection**. Your healthcare team will check the cannula most days and change it on a regular basis.

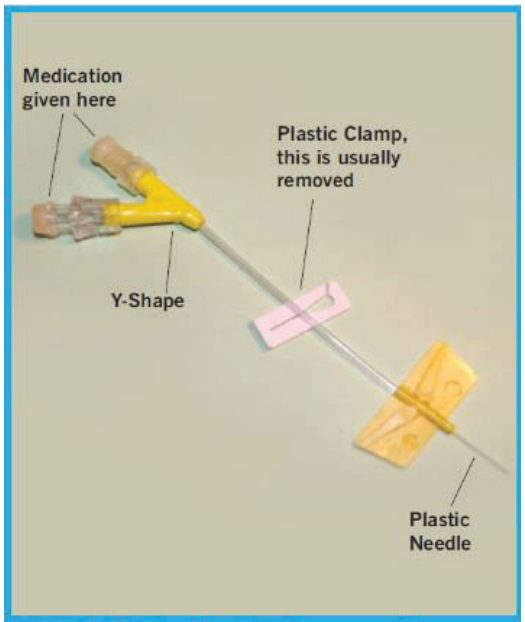

Figure 1: Picture of a subcutaneous cannula also known as a 'Saf-T-Intima™'

If a person is on regular medications, a syringe pump is often connected to the cannula to give medications throughout the day and night to keep symptoms controlled. The person may experience some symptoms even when this is in place – these are called 'breakthrough' symptoms and the most common are pain, agitation, nausea and noisy breathing (rattle). When this happens, a family member/friend is advised to call a healthcare professional (HCP), usually a district nurse. The nurse will visit and give the patient an extra dose of medication using

the cannula that is already in place. These are sometimes called "**as-needed**" medications. It can take a long time, often much more than an hour, for the nurse to arrive, prepare and give the medication. This wait can be distressing for patient and carer.

Giving injections through the cannula that is already in place is usually less painful than an injection into muscle and easier to give. We want to find out whether it is useful and practical for a friend/family member who is involved in the person's care to learn to do this instead of having to wait for a nurse to attend. This person acting as a carer would be trained and educated by a healthcare professional to recognise breakthrough symptoms and prepare and give these no-needle injections to manage these symptoms. This method of teaching carers to do this has been used successfully in parts of Australia for many years. We are working with the team from Brisbane who pioneered it. We cannot be sure that this approach would be welcomed in the UK or if it will be useful and practical for UK patients and their loved ones. That is why we need to test it out and find out what these people think.

When there is uncertainty about whether something works well, the best way to find out is to do a **randomised controlled trial**. This is a test where, at random, half the people receive 'usual care' and the other half the 'new care'. Before doing a large trial, it is good practice to check that it is 'doable' – that it is something patients and their carers want to take part in, that the aims of the project are realistic and achievable, and that a larger trial in the future would be able to give a definite answer about which treatment is better. These smaller studies are known as feasibility studies. The CARiAD project is one such feasibility study.

What is involved if we decide to take part?

If you decide that that you are interested in taking part then we will ask you who you would like to act as your carer for the study. This person will record information about your breakthrough symptoms in a daily diary. If you are in the 'new care' arm, this person will be trained to give you subcutaneous injections for breakthrough symptoms. This person should be a family member or friend who is involved in your day-to-day care, but not anyone who is being paid to provide care for you. We will then approach the carer you have identified and give them information about the study and what it involves for them. It is important to remember that taking part is voluntary, and both you and your carer must want to take part.

If you and your carer decide to take part, you will both be asked to sign consent forms. These forms confirm you have read this information and understand what the project will involve for you – this is called **informed consent**. You can discuss this with other family members, friends or your healthcare team before you decide. Copies of the consent forms will be included in your medical notes. We will contact your GP to let them know you are taking part in the trial.

Because the CARiAD project is a randomised controlled trial, half of the people who decide to take part will receive 'usual care' and half will receive 'new care'. This means that even if you take part, your care might stay the same and your carer will not be able to give you medications for breakthrough symptoms.

'Usual care'

If you and your carer are in the 'usual care' group your carer will call their district nurse (or other healthcare professional) when you have breakthrough symptoms.

'**New care'**

If you and your carer are in the 'new care' group your carer will be trained by the nurses to recognise breakthrough symptoms, prepare and give no-needle injections at home. The professional training given to your carer is very important, in order to make sure that you are given the correct care for breakthrough symptoms. Therefore, your carer should not try to train anyone else who is helping to look after you. If the carer who has been trained by the nurses is not available for any reason, the healthcare team should be contacted to give you any as-needed medication. Trained carers can also choose to call the healthcare team and wait for them to give the injection, or they can give the injection themselves and ask the nurse to check on you later. If you are admitted to a hospital at any stage during the study, the medical team there will handle the management of all your medications (including those for breakthrough symptoms). Your carer should not give you any no-needle injections whilst you are in the hospital.

Patients in both groups will receive all their **regular** healthcare visits and medication as normal. The only thing that could change is who gives the medication for breakthrough symptoms. The group you are in will be chosen for you at random using a computer; the healthcare team will not know beforehand which group you will be in.

Carers in both groups will be asked to keep a diary of symptoms and treatments

and to complete a questionnaire every other day during the trial. If you are well enough, you will help your carer fill the diary in by answering questions about your breakthrough symptoms and how long it takes for them to improve. Your carer can choose to be invited to take part in an interview with a researcher about their experiences of being a carer, being in the trial and giving injections (if in the 'new care' group).

It is important to know that it is completely legal for carers to give symptom-relieving medications as long as they are supported to do so. Our Australian partners have a time-tested education package; we have already reworked this for UK patients, carers and doctors and nurses. This has been done through a series of workshops with experts including patients and their carers.

What happens if we decide not to take part?

Taking part is entirely voluntary. You and your carer should not feel under any pressure from your healthcare team, the researchers or your family/friends to take part if you do not want to.

If you or your carer decide the project is not for you then there will be no effect on your care. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you withdraw and have already completed some of the diary, you can decide if we include this in our findings or if you would prefer us not to. If you are in the 'new care' group and want to withdraw from the trial your carer will need to call the district nurse as usual to treat any further breakthrough symptoms that you might experience.

What if am too ill to give informed consent?

Some people may become confused or disorientated as their illness progresses. This can be a result of their illness or the treatment for it. These people may lose the ability to understand information about the trial. Other people might get more sleepy and weak as their illness progresses and they may not be able to communicate clearly anymore. In these cases, it is not possible for the person to tell us that they are happy still to be included in the trial, which is an important part of informed consent. We want to make sure that everyone is given the same opportunities to take part in the trial and that we

act in their best interests at all times. To help with this, we will ask you to identify someone who knows you well and has an interest in your welfare to act as a **consultee**. This can be your carer, family member, close friend or your GP. The consultee will be asked to confirm that, if you become too ill to communicate with us, you would still want to take part in the trial. You should discuss this with the consultee and tell them your wishes.

What support will we have?

Everyone who takes part in the trial will be able to access support via the usual route for their area. Regular visits from the healthcare team will continue as usual.

If you are in the 'new care' group, your carer will be given thorough and detailed training on how to recognise breakthrough symptoms and to give the no-needle injections. If they are uncertain about what to do they can still call for assistance at any time.

What are the benefits of taking part?

We cannot guarantee that there will be any specific benefits of taking part in this trial, but the information you give us will help us to understand if it is possible to undertake a larger trial in the future.

If you are in the 'new care' group and your carer is trained to give injections at home, it might mean that symptoms are treated more quickly. Sometimes carers tell us that they feel powerless when they see that a person they care about is suffering. Being able to give injections for breakthrough symptoms might mean they feel there is something practical they can do to help.

People who take part in studies like these often report that they were pleased that the trial could help people in future.

What are the possible risks of taking part?

We do not expect any problems with the drugs that will be used in this trial because they are the same as those used in standard practice and are well-tolerated. The drugs used are very commonly given to seriously ill patients to control symptoms and, if you are in the 'new care' group, a nurse will give your carer very detailed training on how to give the no-needle injections at home using the cannula that is already in place. Your carer will have access to support and information at all times. If you have any concerns

about them taking on this extended role you can discuss this with your healthcare team or the trial team.

If you are in the 'new care' group the person caring for you will be able to give you injections for breakthrough symptoms when you are very ill and near the end of your life. This might mean that the time when you die is near to when they have last given you medication. It is very important for the person caring for you to know that these two things are not related.

We don't expect there to be a problem but the healthcare professionals working on the trial will monitor you regularly. If the doctors believe that participation in this trial causes unnecessary risks, you will be removed from the research. In addition, the healthcare professionals have insurance should anything happen to you because of negligence.

If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this trial, the normal National Health Service complaints procedures will be available to you. If you would like independent support with these procedures please contact:

For participants in Wales contact the Community Health Councils Complaints Advocacy Service on 02920 235 558.
For participants in England contact NHS England on 0300 311 22 33 and ask for your local Patient Advice and Liaison Service (PALS).

What will happen to the results of the trial?

All of the information you give will be kept anonymously, treated confidentially and kept securely for 5 years. Consent forms will be stored securely for 15 years. All paper documentation will be disposed of using a secure document destruction service. Electronic records will be deleted.

The results of the trial will be written up for publication in a medical journal but this will not include the personal details of anyone who took part and readers will not be able to identify you, your carer or your family. The research team will also present the anonymous results at national and international meetings so that the

findings can be used by healthcare professionals and researchers in the future to improve patient care. The results will help us decide whether it is practical to do a larger trial in the future to give a definite answer on whether the training of carers to give injections at home for breakthrough symptoms is beneficial for patients and carers.

Who is organising and funding the research?

CARiAD is fully funded by the National Institute for Health Research, and is led by the North Wales Centre for Primary Care Research at Bangor University.

Who has reviewed the trial?

We have discussed our trial with patients and carers. They are greatly in favour of it and have given us their views, particularly with regard to the kind of information we should collect. Two members of our trial team are bereaved carers, and one has administered injections to her loved one. They have helped to design the trial and will be involved throughout the trial. The trial has been reviewed and given approved by the Wales Research Ethics Committee 1.

We understand that this is a very emotionally sensitive time for you. Please do not hesitate to contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the questionnaire or the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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

Information sheet for consultees

CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home
Information sheet for consultees

You are being asked your opinion about whether someone you know should take part in a research trial. Where possible, we give the information about the trial to the person themselves so they can make the decision about whether to take part – this is known as **informed consent.** For consent to be ethical and valid, the person giving consent must be able to understand information about the research and what it involves, and use or weigh that information as part of the process of making a decision about whether they want to take part.

Your relative/friend is unable to make their own decision on whether to participate in this research or their ability to make this decision is likely to change as their illness progresses. To help decide if they should join the trial, we are asking you for your opinion on whether or not they would want to be involved. You are being asked because you know the person well and have an interest in their welfare.

We want to make sure that everyone is given the same opportunities to take part in the trial and to make sure that we act in their best interests at all times. We want to confirm that, in your opinion, if the person was able to understand the trial information and able to communicate with us they would want to take part. You are not being asked to consent on behalf of the person.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. It might help you to think about what the person involved would have wanted, or they may have already expressed their wishes to you in the past.

If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way.

The following information is the same as would have been provided to your relative/friend.

What is the CARiAD project and why is it needed?

People who are seriously ill and nearing the end of their life may want to be cared for in their own homes. As their illness gets worse they may find it difficult to take medicines by mouth – either because they are experiencing nausea and vomiting or because they are becoming too weak to swallow. In the UK, when this happens, it is usual practice for a **cannula** to be put in – this is a small plastic tube placed under the skin. Once it is in place it can be used to give the person medication under the skin **without** using needles – this is sometimes called a **sub-cutaneous injection**. Your healthcare team will check the cannula most days and change it on a regular basis.

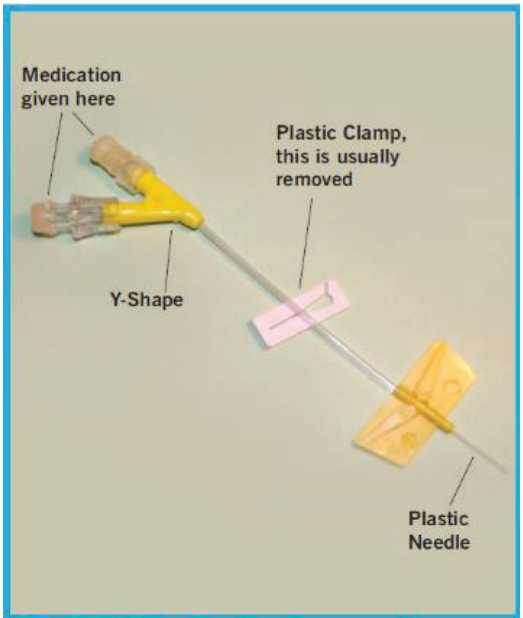

Figure 1: Picture of a subcutaneous cannula also known as a 'Saf-T-Intima™'

If a person is on regular medications, a syringe pump is often connected to the cannula to give medications throughout the day and night to keep symptoms controlled. The person may experience some symptoms even when this is in place – these are called 'breakthrough' symptoms and the most common are pain, agitation, nausea and noisy breathing (rattle). When this happens, a family member/friend is advised to call a healthcare professional (HCP), usually a district nurse. The nurse will visit and give the patient an extra dose of medication using the cannula that is already in place. These are sometimes called "**as-needed**" medications. It can take a long time, often much more than an hour, for the nurse to arrive, prepare and give the medication. This wait can be distressing for patient and carer.

Giving injections through the cannula that is already in place is usually less painful than an injection into muscle and easier to give. We want to find out whether it is useful and practical for a friend/family member who is involved in the person's care to learn to do this instead of having to wait for a nurse to attend. This person acting as a carer would be trained and educated by a healthcare professional to recognise breakthrough symptoms and prepare and give these no-needle injections to manage these symptoms. This method of teaching carers to do this has been used successfully in parts of Australia for many years. We are working with the team from Brisbane who pioneered it. We cannot be sure that this approach would be welcomed in the UK or if it will be useful and practical for UK patients and their loved ones. That is why we need to test it out and find out what

these people think.

When there is uncertainty about whether something works well, the best way to find out is to do a **randomised controlled trial**. This is a test where, at random, half the people receive 'usual care' and the other half the 'new care'. Before doing a large trial, it is good practice to check that it is 'doable' – that it is something patients and their carers want to take part in, that the aims of the project are realistic and achievable, and that a larger trial in the future would be able to give a definite answer about which treatment is better. These smaller studies are known as feasibility studies. The CARiAD project is one such feasibility study.

What is involved for the people taking part in the trial?

If you believe that the person would like to take part in the trial, and their carer is also willing to take part, you will be asked to sign a declaration form and the carer will sign a consent form. It is important to remember that taking part is voluntary, and both the patient and the carer must want to take part. If you are acting as the person's carer and as their consultee you will be asked to complete both your own consent form and the declaration form. These forms confirm you have read this information and understand what the project will involve. You can discuss this with other family members, friends or your healthcare team before you decide. Copies of the forms will be included in the medical notes of the person being cared for. We will contact their GP to let them know they are taking part in the trial.

Because the CARiAD project is a randomised controlled trial, half of the people who decide to take part will receive 'usual care' and half will receive 'new care'. This means that even if you decide the person would want to take part, their care might stay the same and their carer might not be able to give them medications for breakthrough symptoms.

'Usual care'
Carers in the 'usual care' group your carer will call their district nurse (or other healthcare professional) when you have breakthrough symptoms.

'**New care'**
Carers in the 'new care' group your carer will be trained by nurses to recognise breakthrough symptoms, prepare and give no-needle injections at home. The professional training given to the carer is very important, in order to make sure that the

patient is given the correct care for breakthrough symptoms. Therefore, the carer should not try to train anyone else who is helping to look after the patient. If the carer who has been trained by the nurses is not available for any reason, the healthcare team should be contacted to give any as-needed medication. Carers can still call a nurse and wait for them to give the injection, or they can give the injection themselves and ask the nurse to check on the patient later. If the patient is admitted to a hospital at any stage during the study, the medical team there will handle the management of all their medications (including those for breakthrough symptoms). The carer should not give the patient any no-needle injections whilst they are in the hospital.

Patients in both groups will receive all their **regular** healthcare visits and medication as normal. The only thing that could change is who gives the medication for breakthrough symptoms. The group the person is in will be chosen at random using a computer; the healthcare team will not know beforehand which group they will be in.

Carers in both groups will be asked to keep a diary of symptoms and treatments and to complete a questionnaire every other day during the trial. The carer can choose to be invited to take part in an interview with a researcher about their experiences of being a carer, being in the trial and giving injections (if in the 'new care' group).

It is important to know that it is completely legal for carers to give symptom-relieving medications as long as they are supported to do so. Our Australian partners have a time-tested education package; we have already reworked this for UK patients, carers and doctors and nurses. This has been done through a series of workshops with experts including patients and their carers.

What happens if I decide my relative/friend would not want to take part?

Taking part is entirely voluntary. You should not feel under pressure to advise that your friend/relative would want to take part and should consider only what you think their wishes would be. Carers should also not feel under any pressure from the healthcare team, the researchers or family/friends to take part if they do not want to.

If you decide your friend/relative would not want to take part there will be no effect on their care. If you decide they would want to take part you are still free to change your mind and advise us that your friend/relative would wish to withdraw from the trial at any time and without giving a reason. We will then withdraw your friend/relative from

the trial. If data has already been collected, you can decide if we include this in our findings or if you would prefer us not to. If the person is in the 'new care' group and they are withdrawn from the trial their carer will need to call the district nurse as usual to treat any further breakthrough symptoms that the patient might experience.

What support is available to the people taking part?

Everyone who takes part in the trial will be able to access support via the usual route for their area. Regular visits from the healthcare team will continue as usual.

If they are in the 'new care' group, the carer will be given detailed training on how to recognise breakthrough symptoms and to give the no-needle injections. If they are uncertain about what to do they can still call for assistance at any time.

What are the benefits of taking part?

We cannot guarantee that there will be any specific benefits of taking part in this trial, but the information patients and their carers give us will help us to understand if it is possible to undertake a larger trial in the future.

Carers in the 'new care' group who are trained to give injections at home might find that symptoms are treated more quickly. Sometimes carers tell us that they feel powerless when they see that a person they care about is suffering. Being able to give injections for breakthrough symptoms might mean they feel there is something practical they can do to help.

People who take part in trials like these often report that they were pleased that the trial could help people in future.

What are the possible risks of taking part?

We do not expect any problems with the drugs that will be used in this trial because they are the same as those used in standard practice and are well-tolerated. The drugs used are very commonly given to seriously ill patients to control symptoms and, for those in the 'new care' group, a nurse will give the carer very detailed training on how to give the no-needle injections at home using the cannula that is already in place. Carers will have access to support and information at all times.

There may come a time when the carer is giving the injections when the person they are caring for is very ill and will soon die. This might mean that the time when they die is near to when the carer has last given them medication. It is very important to know that these two things are not related and the medication has not ended the persons life.

We don't expect there to be a problem but the healthcare professionals working on the trial will monitor participants regularly. If the doctors believe that participation in this trial causes unnecessary risks, they will be removed from the research. In addition, the healthcare professionals have insurance should anything happen because of negligence.

If you are unhappy or dissatisfied about any aspect of the trial, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution. Regardless of this, if you wish to make a complaint about any aspect of the way you or your relative/friend have been approached or treated during the course of this trial, the normal National Health Service complaints procedures will be available to you. If you would like independent support with these procedures please contact:

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For participants in England contact NHS England on 0300 311 22 33 and ask for your local Patient Advice and Liaison Service (PALS).

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All of the information you give will be kept anonymously, treated confidentially and kept securely for 5 years. Consent forms will be stored securely for 15 years. All paper documentation will be disposed of using a secure document destruction service. Electronic records will be deleted.

The results of the trial will be written up for publication in a medical journal but this will not include the personal details of anyone who took part and readers will not be able to identify the patient, their carer or their family. The research team will also present the anonymous results at national and international meetings so that the findings can be used by healthcare professionals and researchers in the future to improve patient care. The results will help us decide whether it is practical to do a larger trial in the future to give a definite answer on whether the

training of carers to give injections at home for breakthrough symptoms is beneficial for patients and carers.

Who is organising and funding the research?

CARiAD is fully funded by the National Institute for Health Research, and is led by the North Wales Centre for Primary Care Research at Bangor University.

Who has reviewed the trial?

We have discussed our trial with patients and carers. They are greatly in favour of it and have given us their views, particularly with regard to the kind of information we should collect. Two members of our trial team are bereaved carers, and one has administered injections to her loved one. They have helped to design the trial and will be involved throughout the trial. The trial has been reviewed and given approved by the Wales Research Ethics Committee 1.

If at any time you have questions regarding the questionnaire or the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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Information sheet for carers

CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home.
Information sheet for carers

We would like to invite you and the person you are caring for to take part in the CARiAD project. The project is about training carers who are looking after a very ill person at home to give extra doses of medication under the skin to the person they are caring for when they experience breakthrough symptoms. The healthcare team of the person you are caring for have chosen you as someone who might want to take part in this trial. This is because you are involved in the care of a person who is seriously ill, and wants to spend their last days of life at home.

What is the CARiAD project and why is it needed?

People who are seriously ill and nearing the end of their life may want to be cared for in their own homes. As their illness gets worse they may find it difficult to take medications by mouth – either because they are experiencing nausea or vomiting or because they are becoming too weak to swallow. In the UK, when this happens, it is usual practice for a **cannula** to be put in – this is a small plastic tube placed under the skin. Once it is in place it can be used to give the person medication under the skin **without** using needles – this is sometimes called a **subcutaneous injection**. The healthcare team check the cannula most days and change it on a regular basis.

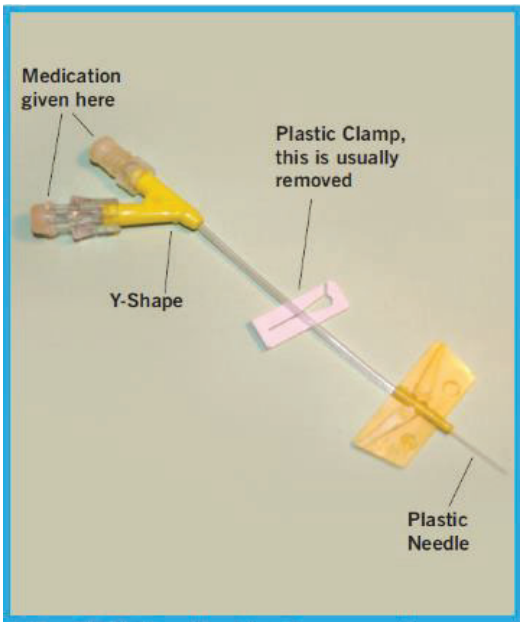

Figure 1: Picture of a subcutaneous cannula also known as a 'Saf-T-Intima™'

If a person is on regular medications, a syringe pump is often connected to the cannula to give these medications throughout the day and night to keep symptoms controlled. The person may experience some symptoms even when this is in place – these are called 'breakthrough' symptoms and the most common are pain, agitation, nausea and noisy breathing (rattle). When this happens, a friend/family member is advised to call a healthcare professional (HCP), usually a district nurse. The nurse will visit and give the patient an extra dose of medication using the cannula that is already in place. These are sometimes called "**as-needed**" medications. It can take a long time, often much more than an hour, for the nurse to arrive, prepare and give the medication. This wait can be distressing for patient

and carer.

Giving injections through the cannula that is already in place is usually less painful than an injection into muscle and easier to give. We want to find out whether it is useful and practical for a friend/family member who is involved in the person's care to learn to do this instead of having to wait for a nurse to attend. This person acting as a carer would be trained and educated by a healthcare professional to recognise breakthrough symptoms, and prepare and give these no-needle injections. This method of teaching carers to do this has been used successfully in parts of Australia for many years. We are working with the team from Brisbane who pioneered it. We cannot be sure that this approach would be welcomed in the UK, or if it will be useful and practical for UK patients and their carers. That is why we need to test it out and find out what you think.

When there is uncertainty about whether something works well, the best way to find out is to do a **randomised controlled trial**. This is a test where, at random, half the people taking part receive 'usual care' and the other half the 'new care'. Patients and carers from both groups can then give us information about their experiences for us to compare. Before doing this in a large trial, it is good practice to check in a smaller trial that it is 'do-able.' We can check that it is something patients and their carers want to take part in, that the aims of the project are realistic and achievable, and that a larger trial in the future would be able to give a definite answer about which treatment is better. These smaller studies are known as feasibility studies. The CARiAD project is such a feasibility study.

What is involved if we decide to take part?

If you and the person you are caring for decide together that you would like to take part then you will both be asked to sign consent forms. These forms confirm you have read this information and understand what the project will involve for you – this is called **informed consent**. It is important to remember that taking part is voluntary, and both you and the person you are caring for must want to take part. You can discuss this with other family members, friends or your healthcare team before you decide. Copies of the consent forms will be included in the medical notes of the person you are caring for so that their healthcare team knows they are in the trial. We will also contact their GP to let them know they are taking part.

Because the CARiAD project is a randomised controlled trial, half of the people who decide to take part will receive 'usual care' and half will receive 'new care'. This means that even if you take part, the person's care might stay the same and you will not be able to give medications for breakthrough symptoms yourself.

'Usual care'

If you are in the 'usual care' group you will call the district nurse (or other healthcare professional) when the person you are caring for has breakthrough symptoms.

'**New care'**

If you are in the 'new care' group you will be trained by the nurses to recognise breakthrough symptoms, prepare and give no-needle injections at home. The professional training given to you is very important, in order to make sure that you are able to give the correct care for breakthrough symptoms. Therefore, you should not try to train anyone else who is helping to look after the person you are caring for. If you are not available to give a no-needle injection for any reason, the healthcare team should be contacted to give any as-needed medications. You can also still call the healthcare team yourself at any time. If the person you are caring for is admitted to a hospital at any stage during the study, the medical team there will handle the management of all their medications (including those for breakthrough symptoms). You should not give them any no-needle injections whilst they are in the hospital.

Patients in both groups will receive all their **regular** healthcare visits and medication as normal. The only thing that could change is who gives the medication for breakthrough symptoms. The group you are in will be chosen for you at random using a computer; the healthcare team will not know beforehand which group you will be in.

Carers in both groups will be asked to keep a diary of symptoms and treatments and to complete a questionnaire every other day during the trial. You will also be visited by a research nurse after the person you are caring for has passed away. You will be asked about symptoms the person experienced. Some carers from each group will be contacted again 2-4 months after the person you are caring for has passed away. These carers will be invited to take part in an interview with a researcher about their experiences of being a carer, being in the trial and giving injections (if in the 'new care' group). You can decide if you want to be invited to these interviews or not.

It is important to know that it is completely legal for carers to give symptom-relieving medications to dying patients as long as they are supported to do so. Our Australian partners have a time-tested education package; we have already adapted this for UK patients, carers and doctors and nurses. This has been done through a series of workshops with experts including carers who have experience of caring for a dying relative.

What happens if we decide not to take part?

Taking part is entirely voluntary. You and the person you are caring for should not feel under any pressure from your healthcare team, the researchers or your family/friends to take part if you do not want to.

The treatment of the person you are caring for will not be affected if you decide not to take part. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. If you withdraw and have already completed some of the diary and questionnaires, you can decide if we include this in our findings or if you would prefer us not to. If you are in the 'new care' group and want to withdraw from the trial you will need to call the district nurse as usual for any further breakthrough symptoms that the patient experiences.

If you or the person you are caring for decide not to take part in this trial, you can still take part in the interview process and share your experiences of being a carer. Please let your healthcare team know if you would like to do this, or contact the research team directly.

What if the person I am caring for is too ill to give informed consent?

When a person gives consent to take part in a research trial it is important that they are able to understand the information they are given and make their own decisions. This is sometimes referred to as their **mental capacity.**

People who are approaching the end of their life may be confused or disorientated as a result of their illness or treatment. They may not be able to understand information about the trial. Other people might get more sleepy and weak as their illness progresses and they may not be able to communicate clearly anymore. In these cases, it is not

possible for the person to give informed consent because they do not have mental capacity. However, it is important that they are given the same opportunities as everyone else to take part in the trial.

To make sure that we act in the best interests of the person being cared for at all times, we will ask someone who knows the patient well and has an interest in their welfare to act as a **consultee.** This may be yourself or another family member or close friend but if this isn't possible we can approach their GP to fulfil this role. The consultee will be asked to confirm that if the person had mental capacity, they would want to take part. If the person you are caring for has capacity to give consent we will ask them to identify someone who can act as a consultee for them. The consultee can then confirm the person's wishes when their illness progresses and they lose capacity.

What support will we have?

Everyone who takes part in the trial will be able to access support via the usual route for their area. Regular visits from the person's healthcare team will continue as usual.

If you are in the 'new care' group you will be given detailed training on how to recognise breakthrough symptoms and to give the no-needle injections. If you are uncertain about what to do you can still call for assistance at any time.

What are the benefits of taking part?

We cannot guarantee that there will be any specific benefits of taking part in this trial, but the information you give us will help us to understand if it is possible to undertake a larger trial in the future.

If you are in the 'new care' group and are trained to give injections at home, it might mean that symptoms are treated more quickly. Sometimes carers tell us that they feel powerless when they see that the person they are caring for is suffering. Being able to give injections yourself might mean that there is something practical you can do to help.

People who take part in studies like these often report that they were pleased that the trial could help people in future.

What are the possible risks of taking part?

We do not expect any problems with the drugs that will be used in this trial because they are the same as those used in standard practice and are generally well-tolerated. The drugs used are very commonly given to seriously ill patients to control symptoms and, if you are in the 'new care' group, a nurse will give you very detailed training on how to give the no-needle injections at home using the cannula that is already in place. You will have information with you at home and will always be able to call a district nurse for help, no matter what group you are in.

There may come a time when you are giving the injections when the person you are caring for is very ill and will soon die. This might mean that the time when they die is near to when you have last given them medication. It is very important for you to know that these two things are not related and the medication has not ended their life.

Whilst we don't expect there to be a problem, the healthcare professionals working on the trial will monitor participants regularly. If they believe that participation in this trial causes unnecessary risk, participants will be removed from the research. In addition, the healthcare professionals have insurance should anything happen to you because of negligence.

If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this trial, the normal National Health Service complaints procedures will be available to you. If you would like independent support with these procedures please contact:

For participants in Wales contact the Community Health Councils Complaints Advocacy Service on 02920 235 558.
For participants in England contact NHS England on 0300 311 22 33 and ask for your local Patient Advice and Liaison Service (PALS).

What will happen to the results of the trial?

All of the information you give will be kept anonymously, treated confidentially and kept securely for 5 years. Consent forms will be stored securely for 15 years. All

paper documentation will be disposed of using a secure document destruction service. Electronic records will be deleted.

The results of the trial will be written up for publication in a medical journal. This will not include the personal details of anyone who took part and readers will not be able to identify you or the person you are caring for. The research team will also present the anonymous results at national and international meetings so that findings can be used by healthcare professionals and researchers in the future to improve patient care. We can also send you a summary of the trial findings if you would like to see them. The results will help us decide whether it is practical to do a larger trial in the future to give a definite answer on whether the training of carers to give injections at home for breakthrough symptoms is beneficial for patients and carers.

Who is organising and funding the research?

CARiAD is fully funded by the National Institute for Health Research, and is led by the North Wales Centre for Primary Care Research at Bangor University.

Who has reviewed the trial?

We have discussed our trial with patients and carers. They are greatly in favour of it and have given us their views, particularly with regard to the kind of information we should collect. Two members of our trial team are bereaved carers, and one has administered injections to her loved one. They have helped to design the trial and will be involved throughout the trial. The trial has been reviewed and approved by the Wales Research Ethics Committee 1.

We understand that this is a very emotionally sensitive time for you. Please do not hesitate to contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

Contact details

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This project was funded by the National Institute for Health Research HTA Programme (project number 15/10/37).

Funded by NHS National Institute for Health Research

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

Information sheet for carer interviews

CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home.
Information sheet for carer interviews

We would like to invite you to take part in a one-to-one interview about your experiences as a carer of a seriously ill person who expressed a wish to spend their last days of life at home. You are being invited to take part in this interview as part of the CARiAD research study. This is because you have recently participated in this study or were approached to take part.

What is the CARiAD project?

People who are seriously ill and nearing the end of their life may want to be cared for in their own homes. As their illness gets worse they may find it difficult to take medications by mouth – either because they are experiencing nausea or vomiting or because they are becoming too weak to swallow. In the UK, when this happens, it is usual practice for a **cannula** to be put in – this is a small plastic tube placed under the skin. Once it is in place it can be used to give the person medication under the skin **without** using needles – this is sometimes called a **subcutaneous injection**. The healthcare team check the cannula most days and change it on a regular basis.

If a person is on regular medications, a syringe pump is often connected to the cannula to give these medications throughout the day and night to keep symptoms controlled. The person may experience some symptoms even when this is in place – these are called 'breakthrough' symptoms and the most common are pain, agitation, nausea and noisy breathing (rattle). When this happens, a friend/family member is advised to call a healthcare professional (HCP), usually a district nurse. The nurse will visit and give the patient an extra dose of medication using the cannula that is already in place. It can take a long time, often much more than an hour, for the nurse to arrive, prepare and give the medication. This wait can be distressing for patient and carer.

In some parts of the world such as Australia, carers are trained and educated by the district nurses to recognise breakthrough symptoms, and prepare and give these extra doses by "no-needle" subcutaneous injection. The CARiAD project is a study to see if an established Australian training package can be adapted for use in the UK.

We want to test if it is feasible and acceptable to UK patients, carers and healthcare professionals. As part of this, we want to find out about the experiences of people who took part in the study, and those who decided that they did not want to take part.

Why have I been chosen to take part?

You have been invited to take part because you took part in the CARiAD study and have indicated that you would like to be invited to interview and share your experiences of being a carer and being in the study.

What is involved if I decide to take part?

Participation is entirely voluntary and you may withdraw at any time. You will be given time to consider this information sheet and a researcher will then contact you to confirm if you would like to take part. If you decide that this is something you would like to do, the researcher will arrange a time and place to visit you to conduct the interview – this will usually be in your own home or at a suitable alternative place if you would prefer. You will be asked to complete a consent form on the day indicating that you understand what the study is about and agree to take part.

Interviews will consist of two parts. The first part will last 30-60 minutes and the researcher will ask you questions about your experiences of being a carer for someone in the last days of life and your experiences of taking part in the CARiAD trial.

In the second part of the interview you will be asked about different factors that are important when guiding your choices between having a healthcare professional to administer as-needed subcutaneous medication to the person you are caring for or being able to do this yourself. This part of the interview will last around 20 minutes.

The interviews will be audio recorded. This will allow the discussion to be transcribed into print and analysed by researchers at Bangor University. If you do not want to take part you can contact the study team using the details at the end of this information sheet to let them know, or you can tell the researcher when they call you.

Will my taking part be kept confidential?

All information collected will be kept strictly confidential. However, the research

team are under a statutory obligation to break confidentiality where cases of malpractice, abuse, or risk to self or others are disclosed. Such cases will be referred to the appropriate authority.

You will not be personally identifiable in any typed transcription or in any subsequent verbal or written account. Anonymised quotes from the interview may be used in future publications but you will not be identifiable. Recordings will not be heard by anyone other than the CARiAD research team and the Bangor University approved transcribers. The audio recordings will be transferred to secure, password protected computers at Bangor University. Recording devices will be checked to ensure all recorded material has been erased. Audio recordings will be erased from the computers five years after the study has ended.

What are the possible disadvantages and risks of taking part?

Whilst we do not foresee any problems we appreciate that it may be distressing for you to discuss some of your experiences of caring for a seriously ill person. If you find the interview too difficult you are able to pause or stop it at any time.

What are the possible benefits of taking part?

Although there are no direct benefits to you of taking part in this study, the information you give us will be used to support the research into extending the role of carers to include administering subcutaneous medication. This may help improve patient and carer experiences in the future.

What will happen to the results of the study?

All of the information you give will be kept anonymously, treated confidentially and kept securely for 5 years. Consent forms will be stored securely for 15 years. All paper documentation will be disposed of using a secure document destruction service. Electronic records will be deleted.

The results of the study will be written up for publication in a medical journal. This will not include the personal details of anyone who took part and readers will not be able to identify you or the person you are caring for. The research team will also present the anonymous results at national and international meetings so that findings can be used by healthcare professionals and researchers in the future to improve patient care. We can also send you a summary of the study findings if you would like to see them. The results will help us decide whether it is practical to do a

larger trial in the future to give a definite answer on whether the training of carers to give injections at home for breakthrough symptoms is beneficial for patients and carers.

Who is organising and funding the research?

CARiAD is fully funded by the National Institute for Health Research, and is led by the North Wales Centre for Primary Care Research at Bangor University.

Who has reviewed the study?

We have discussed our study with patients and carers. They are greatly in favour of it and have given us their views, particularly with regard to the kind of information we should collect. Two members of our study team are bereaved carers, and one has administered injections to her loved one. They have helped to design the study and will be involved throughout the study. The study has been reviewed and approved by the Wales 1 Research Ethics Committee.

We understand that this is a very emotionally sensitive time for you. Please do not hesitate to contact our study manager, Stella Wright, to discuss your participation in the study.

Thank you for taking the time to read and consider this information.

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

Information sheet for interviews for people who declined to participate (in the pilot trial)

CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home.
Information sheet for interviews people who declined to participate

You have recently been invited, and declined, to take part in a study called CARiAD. We would like to understand why people decline to be involved and are inviting you to take part in a one-to-one interview to help us understand your reasons for this. This will help us design the study better in future.

Why have I been chosen to take part?

You have been invited to take part because you were approached to take part in the CARiAD study and declined.

What is involved if I decide to take part?

If you agree to take part you will be interviewed by the study researcher about your reasons for not wanting to take part in the CARiAD study. There will be no pressure or attempt whatsoever to encourage you to take part in the CARiAD study. The interview is simply to understand why people do not want to participate, so that we can improve the study in the future.

Interviews will consist of two parts. The first part will last about 15-20 minutes and focus on your reasons for not wishing to take part in the main trial.

In the second part of the interview you will be asked about different factors that might be important when guiding your choices between having a healthcare professional to administer as-needed subcutaneous medication to the person you are caring for or being able to do this yourself. This part of the interview will last around 20 minutes.

The researcher will come to your home to conduct the interview, or to another venue if you prefer. The interview will be audio recorded and transcribed into print and analysed by researchers at Bangor University.

Will my taking part be kept confidential?

All information collected will be kept strictly confidential. However, the research team are under a statutory obligation to break confidentiality where cases of

malpractice, abuse, or risk to self or others are disclosed. Such cases will be referred to the appropriate authority.

You will not be personally identifiable in any typed transcription or in any subsequent verbal or written account. Anonymised quotes from the interview may be used in future publications but you will not be identifiable. Recordings will not be heard by anyone other than the CARiAD research team and the Bangor University approved transcribers. The audio recordings will be transferred to secure, password protected computers at Bangor University. Recording devices will be checked to ensure all recorded material has been erased. Audio recordings will be erased from the computers five years after the study has ended.

What are the possible disadvantages and risks of taking part?

The interviews will focus on your reasons for not taking part in the study, so we do not foresee any problems. However we appreciate it may be distressing for you to discuss caring for a seriously ill person. If you find the interview too difficult you are able to pause or stop it at any time. We expect that the main disadvantage for you will be the 30-40 minutes of your time that you will be committing.

What are the possible benefits of taking part?

Although there are no direct benefits to you of taking part in this study, the information you give us will be used to improve the research study for future phases.

What will happen to the results of the study?

All of the information you give will be kept anonymously, treated confidentially and kept securely for 5 years. Consent forms will be stored securely for 15 years. All paper documentation will be disposed of using a secure document destruction service. Electronic records will be deleted.

The results of the overall CARiAD study will be written up for publication in a medical journal. This will not include the personal details of anyone who took part and readers will not be able to identify you or the person you are caring for. The research team will also present the anonymous results at national and international meetings so that findings can be used by healthcare professionals and researchers in the future to improve patient care. We can also send you a summary of the study findings if you would like to see them. The results will help us decide whether it is practical to do a larger trial in the future to give a definite answer on whether the

training of carers to give injections at home for breakthrough symptoms is beneficial for patients and carers.

Who is organising and funding the research?

CARiAD is fully funded by the National Institute for Health Research, and is led by the North Wales Centre for Primary Care Research at Bangor University.

Who has reviewed the study?

We have discussed our study with patients and carers. They are greatly in favour of it and have given us their views, particularly with regard to the kind of information we should collect. Two members of our study team are bereaved carers, and one has administered injections to her loved one. They have helped to design the study and will be involved throughout the study. The study has been reviewed and approved by the Wales 1 Research Ethics Committee.

We understand that this is a very emotionally sensitive time for you. Please do not hesitate to contact our study manager, Stella Wright, to discuss your participation in the study.
Thank you for taking the time to read and consider this information.

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Funded by NHS National Institute for Health Research

Healthcare Professional invitation

Dear Dr *

Your patient (name / DOB / address) has consented to take part in the CARiAD trial, and has been randomised to the intervention arm. Please read this important information, so you are aware of how your patient's lay carer is taking an extended role in the care of a dying relative or friend.

CARiAD – Carer administration of as-needed sub-cutaneous medication for breakthrough symptoms in homebased dying patients: a UK feasibility study

This is an HTA NIHR funded trial which is running in North and South Wales, and Gloucestershire. It is mainly the District Nurses looking after your patient who will be involved on a day to day basis with training the lay carer, and carrying out the trial procedures. However, we recognise the vital role the GP team play in ensuring anticipatory medication is prescribed, and monitoring / overseeing their care. You don't really need to do anything different in terms of your usual care of the patient; other than knowing they are in the trial. We would be very grateful if you could note the suggested prescribing information we are using for this study (attached). Your patient is in the intervention arm, so, the carer will be trained to give sub-cutaneous PRN medications for the four common symptoms of pain, nausea/vomiting, restlessness and noisy breathing. These will be based on the prescribing information attached.

The lay carer role does not involve the medication given by the syringe driver. An additional butterfly will be inserted to allow a needle-free delivery of PRN doses. The other patients who are in the control arm will receive usual care, and will help us by collecting data and completing outcome measures.

This role extension has been practiced in Australia for over 30 years, and a well evaluated training package developed in Brisbane by our research partners has been modified for UK use. The successful Australian project over-recruited, and was viewed positively by patients, their carers and healthcare professionals, without significant adverse events. CARiAD has been funded to adapt the successful Australian training package for UK carers and to find out whether it is feasible and acceptable for them to administer medication to dying patients for breakthrough symptoms.

It is legal for carers to give subcutaneous medications in the UK and this is happening in small localised areas. This feasibility trial will help decide whether or not to roll out a larger trial.

If you would like more information about CARiAD, please contact:

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Dear Dr *

Your patient (name / DOB / address) has consented to take part in the CARiAD trial, and has been randomised to the control (usual care) arm. Please read this important information, so you are aware of how your patient's lay carer is involved in recording information about the care of a dying relative or friend.

CARiAD – Carer administration of as-needed sub-cutaneous medication for breakthrough symptoms in homebased dying patients: a UK feasibility study

This is an HTA NIHR funded trial which is running in North and South Wales, and Gloucestershire. It is mainly the District Nurses looking after your patient who will be carrying out the trial procedures. However, we recognise the vital role the GP team play in ensuring anticipatory medication is prescribed, and monitoring / overseeing their care. You don't really need to do anything different in terms of your usual care of the patient; other than knowing they are in the trial.

Your patient is in the control arm, so will receive usual care, and their carers will help us by collecting data and completing outcome measures.

For your information, for those patients who are randomised to the intervention arm, the carer will be trained to give sub-cutaneous PRN-only medications for the four common symptoms of pain, nausea/vomiting, restlessness and noisy breathing.

This role extension we are studying has been practiced in Australia for over 30 years, and a well evaluated training package developed in Brisbane by our research partners has been modified for UK use. The successful Australian project over-recruited, and was viewed positively by patients, their carers and healthcare professionals, without significant adverse events. CARiAD has been funded to adapt the successful Australian training package for UK carers and to find out whether it is feasible and acceptable for them to administer medication to dying patients for breakthrough symptoms.

It is legal for carers to give subcutaneous medications in the UK and this is happening in small localised areas. This feasibility trial will help decide whether or not to roll out a larger trial.

If you would like more information about CARiAD, please contact:

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