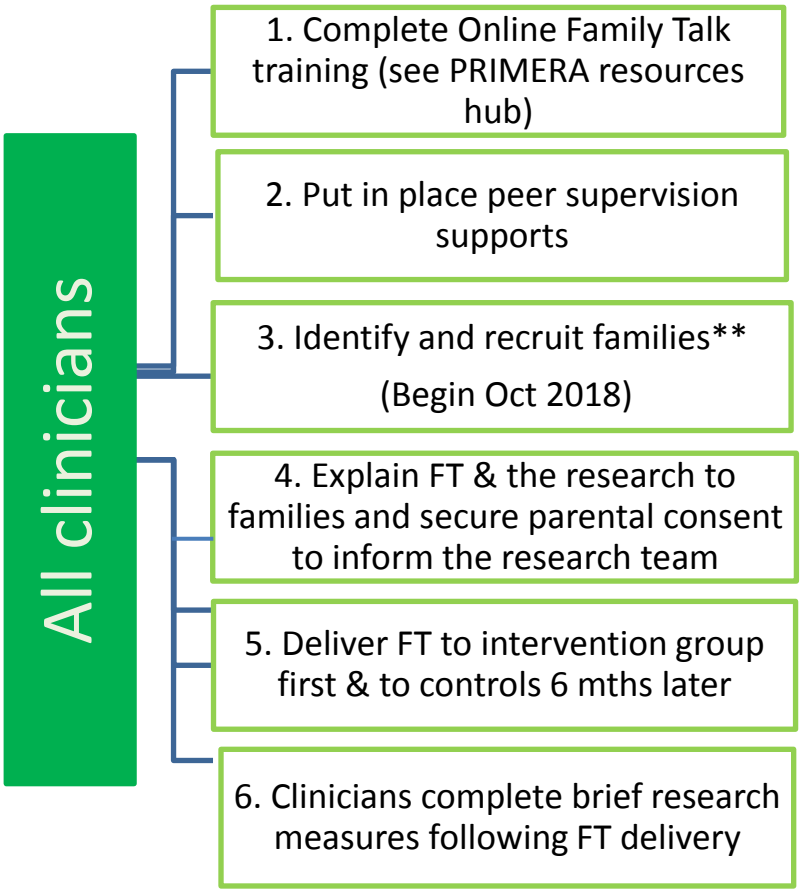
Clinician responsibilities/activities when participating in the PRIMERA research



1. All clinicians who have agreed to deliver Family Talk and to take part in the research, must complete the online Family Talk training on the Emerging Minds website and consult the PRIMERA resources hub on the PRIMERA webpage https://cmhcr.eu/primera-programme/

2. Clinicians should engage in regular peer supervision within/across sites and especially when engaging with the first few families. The lead collaborator/lead contact person within each site is responsible for ensuring that FT is delivered in their area by liaising with, and supporting, their colleagues and identifying any early problems.

3. **It is very important that families are recruited as soon as possible (beginning in October 2018).** The final date for enrolling/entering families to the research is **September 2019**. Ethical approval has been secured from the HSE, Tusla and Saint John of God's and Maynooth University. **Please see further comment below on recruitment.**

4. Family leaflets have been provided to help clinicians explain FT to families using plain language whilst 'clinician' leaflets are also available. In addition, prospective families might be interested in reading the excellent Irish Times article, which outlines Christine's personal story as well as providing a readable introduction to the issue and study. Please also see Appendix 1 for how you might describe FT and the study to families.

5. Families will be randomised to attend FT immediately or in six months' time. Control group families should not be given Family Talk until after the 6-month follow up assessment has been conducted with both intervention group and control group families.

6. We are keen to explore clinicians' views and experiences as part of this research and to this end, we would request your help (at some stage in the future) in completing a brief online survey on the delivery of Family Talk in your service. For example, you should keep a record of sessions attended by families. We would also ask you to keep a record of your hours involved in implementing and delivering Family Talk. You may also be asked to take part in a short interview with a researcher to discuss your experiences of setting up and delivering Family Talk. All of this information will be invaluable in understanding the factors involved in implementing Family Talk and in exploring your experiences and views.

A note on recruitment of families (item 3)

We are keen to emphasise that the identification and recruitment of families should take place as soon as possible. This is important for the following reason:

- The funding for the study ends in early 2021. If most of the recruitment is left towards the end of 2019, that leaves a very limited period of time for the research team to conduct 6- and 12-month follow-up assessments with families. It would also mean that we would still be collecting data towards the end of 2020, leaving precious little time for analysis and writing up and disseminating the findings.

We recommend that clinicians over-recruit families. While clinicians may worry about their capacity to see families, it is far more likely that they will find it difficult to find families. For instance, some families may not be ready to attend at this time or will agree to participate but then drop out. Also, one third of families will be allocated to the control group so the clinician will not see them now (but 6 months later). If possible, we recommend that Family Talk staff share the load in seeing families as one staff member may succeed in recruiting 5 families where other staff may recruit 1-3 families.

We recognise that considerable time, energy and dedication/commitment are required to take part in this research, to engage in training and to deliver FT, but we hope, in turn, that you will see benefits to your service in the short to medium term. We also want to emphasise the time constraints within which

the research team are required to work, and our overarching goal to conduct rigorous research that will help to make a difference. We believe that producing high quality evidence is in the best interests of both families and service providers in order to inform policy and practice in this area. These outcomes are best achieved if all sites endeavour to recruit as many families as possible to the research within the one-year timeframe so that we have a sufficiently large sample from which we can generate robust findings.

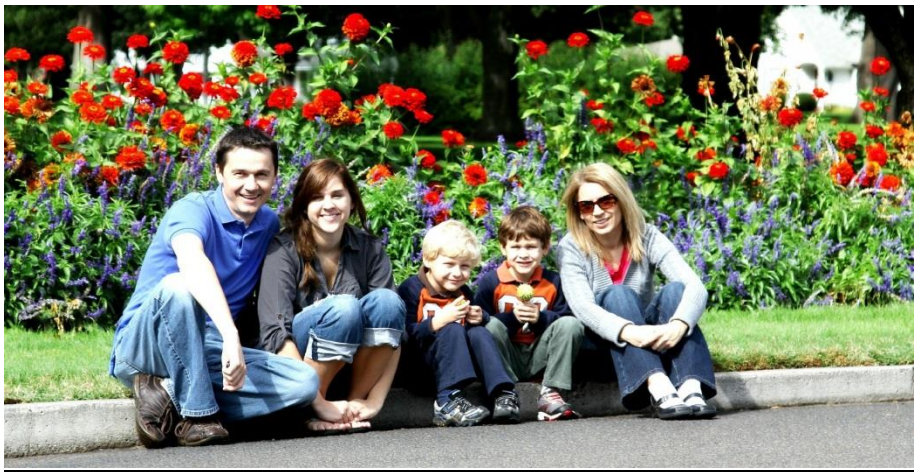
We truly do recognise all of your hard work, to date, in securing buy-in from managers and agreeing to take part in this research, and for that we are very grateful. Importantly, we also hope to capture your experiences in the research. This is a unique opportunity to try and make a real difference for vulnerable families. Many positive 'forces' have aligned in relation to this study in that: substantial funding has been made available to produce an evidence-base to inform policy and practice for these families; many pioneering clinicians around the country have gathered enthusiastically around a common cause; and there is substantial political, organisational and media interest in, and support for, this work. This is our moment if we make the best of it – 'Carpe Diem'! Many thanks and we look forward to continuing to work with you all.

Appendix 1: Engaging with families: A plain language guide to Family Talk and the research

Family Talk

Family Talk involves 6-8 meetings with parents/partners, children and the whole family. FT is suitable for children aged 5-18 years. The purpose of the programme is to help family members talk about mental health difficulties, to support parents, partners and children. It can be delivered in the home or clinic (whatever is best for your service). Use the family brochure to describe the proposed benefits of Family Talk.

The programme developer – Dr Bill Beardslee – advises that the whole family be encouraged to attend. However, at least one parent/guardian and one child must attend. Also, it's up to the family to define 'family'. For example, grandparents, relatives, and/or friends can attend if they are identified as playing a significant role in the family's life. We are especially keen to encourage fathers to attend as they are so often absent from research.



Explaining the research

The purpose of the research is to find out if Family Talk actually helps families. We hope that families will see benefits from attending *Family Talk*, for example, hopefully it will help family members to talk more openly and with understanding about mental health issues. Your information and sharing your experiences of *Family Talk* will be so important in helping government and health services provide better supports for families in Ireland when a parent has mental health difficulties. The evidence gathered will also inform the drafting of policy guidance in the Republic of Ireland on this issue.

- In our experience, families usually enjoy the experience of the research and do not experience it as a burden. They usually feel that they are contributing to something positive on a national and international basis, as well as getting some support for their family.

2:1 chance of getting Family Talk now or in six months

To persuade funders, we need to show them high quality evidence or proof that Family Talk helps families. To do this, the researchers compare results for families who take part in Family Talk, with those who have not yet received the programme, to see if there is a difference between the two in terms of how they are doing. Families will have a 2:1 random chance of taking part in Family Talk immediately or in 6 months' time. So families are twice as likely to attend FT sooner rather than later, but it is decided by chance alone as this is the only fair way to do it. If the family is chosen at random to receive FT approximately 6 months later, they will receive usual services up until that point (e.g. parent attending AMHS/GP/etc).

Another way of phrasing it might be: 'You will receive Family Talk within the next six months but it could be sooner (families are twice as likely to receive it immediately rather than 6 months later).

NB. If clinicians do not feel comfortable in talking about how one in three families will be randomly allocated to have to wait 6 months for Family Talk, it is better that you let Sharon (PRIMERA research fieldwork coordinator) explain this to parents. If this is not explained properly or phrased negatively, it may put parents off. As researchers, we are used to explaining this so if you do not feel comfortable, it is better to leave it to the research team.

In our experience so far in meeting parents at the pre-intervention interview, the parents have understood about receiving Family Talk either now or later. So for the families we've met to date, the randomisation issue has not been a barrier.

- If you absolutely believe that a particular family randomised to the control group must receive something in the interim while waiting for Family Talk, that 'something' could be usual services or a different intervention. However it must not be Family Talk. Or not, in our analysis we would be comparing Family Talk with Family Talk and we would likely not see any differences in outcomes between the two groups!
- If you think that the family in the control group must receive Family Talk now, then that family can receive Family Talk but they would have to be removed from the research. Let us know if that happens.

What will happen to families if they would like to take part in the study?

- Tell families that, with their verbal consent, a researcher will contact them to discuss the research in more detail.
- A researcher will meet with parent 2/3 times over next year. Parents will be asked to complete some questionnaires and the meeting will take approximately one hour. The meeting will usually take place in the parent's home at a time that suits them. Parents will get a €25 voucher each time a researcher meets them[1].

[1] SJOG families will not receive a voucher.

- With the parent's consent, children (aged 8[2]-18 years) will then be invited to fill in a few short questionnaires on an online survey (10-15 mins).[3]

NB. If a family requests to attend FT, but does not wish to be involved in the research, that will have to be allowed. However, this will mean that one less family, in each case, will be included in the research. This may happen in only a small number of cases, but if it is extensive, it will have serious implications in terms of participant recruitment. A smaller number of participating families will mean a less robust evaluation, thereby undermining the case for support being made available for families in the future. **Therefore, FT and the research should be sold as a 'package' (insofar as possible).** The research process is not onerous, is generally enjoyed by families and may sometimes have therapeutic effects. Also, it empowers families to know that they are contributing to something worthwhile beyond themselves that will help other families. Therefore, every effort should be made to engage families to the research process too.

[2] The age range for completing the measures (8-18 years) is different to the age range (5-18 years) at which children are allowed to attend Family Talk. This is because it is very difficult to find outcome measures suitable for children younger than 8 years.

[3] In the SJOG site, a researcher will meet with children 8-12 years in their home, while children 13-18 years will be asked to fill in the questionnaires in an online survey.