

Multiple Sclerosis and Family Planning – A Toolkit for Healthcare Professionals Managing Women with Multiple Sclerosis

Development of the toolkit materials was initiated and funded by Teva Pharmaceuticals

ultiple sclerosis (MS) is more common among women of childbearing age compared with any other age group. Many women with MS are concerned about the impact of pregnancy on their health. This toolkit is designed to support healthcare professionals (HCPs) of women with MS who are considering starting a family. It offers guidance on responses to frequently asked questions and provides patient education materials, which will equip women with MS with information on pregnancy and childbirth.

Keywords

Multiple sclerosis (MS), relapsing forms of MS (RMS), pregnancy, childbearing, childbirth, family planning

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A recent survey of European women aged 25–35 years diagnosed with relapsing forms of multiple sclerosis (RMS) in the last five years showed:

- 88% of survey respondents (n=1,000) were concerned at diagnosis they would not be able
 to have children, despite studies that show they are just as likely to conceive and have
 healthy children as anyone else.¹
- many respondent women with multiple sclerosis (MS) had not spoken with their neurologist/
 MS specialist (35%) or general practitioner (57%) about family planning, despite their concerns.

Wakefield Research conducted a survey for Teva Pharmaceuticals of 1,000 European women aged 25–35 years recently diagnosed with relapsing forms of multiple sclerosis (RMS) to explore attitudes and experiences surrounding family planning. The survey was conducted in Germany, Italy, the Netherlands, Spain, and the United Kingdom. It showed that misconceptions about family planning with multiple sclerosis (MS) persist and underscored the need for better dialogue between women with RMS and healthcare professionals (HCPs).

To address this unmet need, Teva worked with touchNEUROLOGY®, the online publication partner to *European Neurological Review*, to publish a 'MS and Family Planning Toolkit'. The toolkit includes resources to help support more meaningful dialogue on family planning between women with MS and their HCPs. The toolkit features materials for HCPs, such as:

• HCP guide to survey results and patient conversation

It is also comprises materials for patients that may be duplicated and shared at your clinics, on your websites or via any patient communications you distribute:

- family planning questions for women with MS to ask their healthcare team;
- facts on MS and family planning for women with MS; and
- tips for women with MS on family planning.

We hope these materials support you in educating your female MS patients about family planning. A commentary article about the complete survey results is also available:

Manson JM, European women with MS feel unprepared and uneducated about family planning and their ability to have children: how do we improve patient education? *European Neurological Review*. 2018;13(1):Epub ahead of print.

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Healthcare professional guide to survey results and patient conversation

An introduction to this guide

To better understand the beliefs, fears, and awareness around family planning that women with multiple sclerosis (MS) have, Teva Pharmaceuticals conducted a European survey of 1,000 women from Germany, Italy, the Netherlands, Spain and the United Kingdom (UK), recently diagnosed with relapsing forms of MS (RMS). The survey uncovered some misconceptions and lack of knowledge on how MS impacts a woman's ability to have a family, as well as a reticence to fully engage with healthcare professionals (HCPs) on this topic (Wakefield Research for Teva Pharmaceuticals, 10 August to 1 September 2017, data on file).²

This guide has been developed to help HCPs address these findings, and to manage a more meaningful dialogue about family planning with women who have MS. We have included frequently asked questions (FAQs) in this document that correspond with the suggested questions for women to ask their HCPs that are featured in the patient educational materials included in this supplement. This guide does not provide complete responses to any question, but rather includes facts and figures from the medical literature to help you formulate your responses to patients. You have the best knowledge of your individual patients' situation and are in the best position to interpret and answer their questions about family planning with MS. We hope this guide provides a helpful framework.

Family planning counselling should be offered to every female patient with MS of reproductive age, given the high rates of unplanned pregnancies and safety concerns of disease-modifying treatments (DMTs).³

Survey overview

- **Sample:** 1,000 women (200 from each of the 5 countries), aged 25–35 years, diagnosed with relapsing forms of MS in the last 5 years
- **Countries**: Germany, Italy, the Netherlands, Spain and the United Kingdom
- Methodology: E-mail invitation and an online survey between 10 August and 1 September 2017
- Margin of error: ±3.1 percentage points overall and ±6.9 percentage points in each country

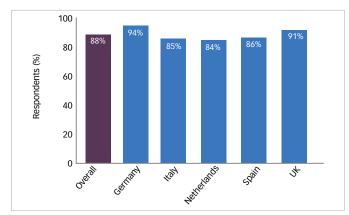
Addressing misconceptions and lack of knowledge

The survey revealed that some misconceptions and lack of knowledge about family planning persist among women with MS from all the countries surveyed.

Although MS is a chronic, progressive neurological disease most prevalent amongst women of childbearing age,⁴ women with MS are just as likely to conceive and have healthy children as the general population.^{1,5} Yet, 88% of the women surveyed had concerns at the time of their diagnosis that they would not be able to have children (*Figure 1*),² which may be due to a lack of knowledge that having children is indeed possible for women with MS.

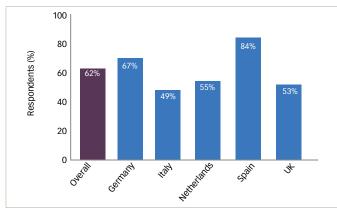
In addition, 62% of women with MS who had any concern about their ability to have children, were also concerned they had the potential to

Figure 1: Percentage of respondent women with MS who had concerns at the time of their diagnosis that they would not be able to have children



Wakefield Research for Teva Pharmaceuticals, 10 August to 1 September 2017, data on file

Figure 2: Percentage of respondent women with MS who had any concern about their ability to have children and were also concerned about the potential to pass on the disease



Wakefield Research for Teva Pharmaceuticals, 10 August to 1 September 2017, data on file

pass the disease on to their children (*Figure 2*).² Although there may be some genetic factors that trigger MS, it is not considered to be hereditary.⁵

Below are pertinent facts related to two key questions women with MS may have after diagnosis about family planning, based on the survey. We have compiled information based on published research to help you respond and clear up any confusion or misconceptions women may have.

Q: Can I still have children now that I have been diagnosed with MS?

- Many women go on to start their families after being diagnosed
 with MS 6
- Fertility does not appear to be affected by MS or by DMT use.⁷
- MS has no significant impact on foetal development or the ability to carry to term.⁵
- The frequency of birth defects and neonatal deaths is not different from that of the general population.^{8,9}

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 Most studies have not found any adverse effect of a pregnancy on long-term disease progression or disability; some even show favourable effects.^{3,10}

Q: What is my child's risk of developing MS?

- Although there may be some genetic factors that trigger MS, it is not considered to be hereditary.⁵
- Children of a parent with MS have a 4.0% risk of developing the condition themselves. The general population has a 0.2% risk of developing MS.¹¹

Improving patient interaction to maximise outcomes

Effective communication between patients and their HCPs has been recognised as a key component in improving patient satisfaction, compliance, and health outcomes.¹² For women with MS, greater understanding about their illness, its treatment, and its impact on family planning, can help them be better informed about their options.²

The confusion about family planning highlighted by the survey may be fuelled by a reluctance among women to fully engage with their HCPs on this topic. Despite their concerns, more than one in three women (35%) in the European countries surveyed who had concerns that they would not be able to have children at the time of their MS diagnosis, had not spoken with their neurologist/MS specialist about family planning. More than half (57%) had not spoken to their general practitioner about family planning (*Figure 3*).²

Women gave the following reasons when asked why they did not speak with their HCP about family planning (n=70; Wakefield Research for Teva Pharmaceuticals, 10 August to 1 September 2017, data on file):

- 49% did not think having a family would be possible;
- 40% weren't comfortable talking to their HCP about it;
- 36% said there wasn't enough time for them to ask.

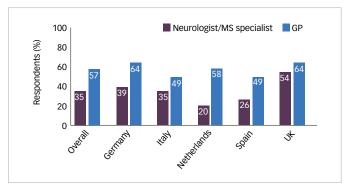
More than four out of five women (81%) said they wished there was more or better information on family planning.² Overall, 82% of respondents identified family planning topics they wished they had covered with their doctor or other healthcare professional at diagnosis, and the most common topics are summarised (*Figure 4*).²

By taking time to proactively bring up and address issues relating to family planning, HCPs can quickly dispel myths, and help patients gain control of this important part of their lives. We have compiled the FAQs below based on the topics women surveyed wished they had covered with their HCPs, as well as input we received from medical experts on the touchNEUROLOGY® editorial board.

Q: If I'd like to get pregnant some day (but not in the near future), what should I start thinking about now?

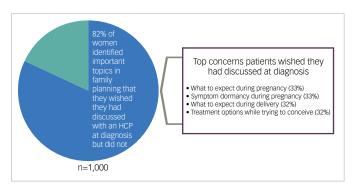
- No DMTs are currently recommended for use while trying to conceive, during pregnancy, or while breastfeeding,⁵ however, a large study from the MSBase global registry reported that prior DMT use, any time in the 2 years before pregnancy, resulted in a 45% decreased risk for post-partum relapse.¹³
- The authors interpreted their study as providing evidence in favour
 of choosing to delay pregnancy, in order to commit to a DMT to
 control disease activity first.¹³ This would be particularly pertinent
 for women with high MS disease activity, greater disability, or a poor
 prognostic profile.⁵

Figure 3: Percentage of respondent women with MS who had concerns at the time of their MS diagnosis that they would not be able to have children, but who had not spoken about it to a healthcare professional



Wakefield Research for Teva Pharmaceuticals, 10 August to 1 September 2017, data on file.

Figure 4: Family planning topics women wished they had discussed with their doctors at diagnosis



Reproduced with permission from Manson JM, 2018.²

Q: Do I need to use contraception while I am on medication?

- Women with MS of childbearing age should be counselled on contraception before they initiate a DMT.⁵
- No DMTs are currently recommended for use while trying to conceive, during pregnancy, or while breastfeeding.⁵

Q: If I want to get pregnant now/in the very near future, what should I start doing now to plan for that?

- Vitamin D deficiency increases risk for MS, and women with MS were shown to have lower vitamin D concentrations during pregnancy and post-partum compared with controls.¹⁴ Vitamin D deficiency should be evaluated and treated prior to pregnancy.⁵
- Any woman with MS seeking to become pregnant should take prenatal vitamins and folic acid, avoid alcohol and smoking, and assure good sleep hygiene and diet.⁵
- No DMTs are currently recommended for use while trying to conceive, during pregnancy, or while breastfeeding.⁵

Q: Can I take prenatal vitamins?

 Any woman with MS seeking to become pregnant should take prenatal vitamins and folic acid, avoid alcohol and smoking, and assure good sleep hygiene and diet. Vitamin D deficiency should also be evaluated and treated prior to pregnancy.⁵

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- Q: Does wanting a family impact my treatment plan?

 / Do I need to stop treatment if I want to get
 pregnant? / Will I be able to stay on my medication
 while I'm trying to conceive? / Will I be able to stay
 on my medication while I'm pregnant?
- No DMTs are currently recommended for use while trying to conceive, during pregnancy, or while breastfeeding.⁵
- Most women should stop DMTs before pregnancy.³
- The current standard of care is to avoid DMT use during pregnancy, and to stop a DMT as soon as pregnancy is recognised.⁵
- In some patients with active disease, treatment may be warranted.¹⁵
 However, the decision to continue a DMT should involve formal documentation of the conversation involving the risks and benefits, and a clear indication that the patient has made this informed decision.⁵

Q: Are any MS symptoms worsened during pregnancy?

- There is a great amount of research to show that women with MS go through healthy pregnancies like the general population.¹
- Most studies have found that pregnancy does not have an adverse effect on disease progression or subsequent disease course – researchers have discovered that pregnancy can have beneficial effects on the mother's health during pregnancy.¹¹
- Research in thousands of women has shown that women with MS tend to experience fewer relapses during pregnancy, particularly in the third trimester.¹¹
- Pregnancy does not expose patients with MS to additional complications apart from an increased predisposition to urinary infections and constipation.¹
- Fatigue may take a bit more managing as a new mother with MS, since tiredness is also a common symptom of MS.¹⁶

Q: Can I remain active/exercise during pregnancy?

- In the general population, moderate- and high-intensity exercise in normal pregnancies is safe for the developing foetus and has several important benefits such as reduction in caesarean section rates, appropriate maternal and foetal weight gain, and managing gestational diabetes. Thus, exercise is recommended according to the woman's pre-conception fitness ability.¹⁷
- While there is very limited research on exercise in pregnant women with MS, other studies have established the benefits of exercise in people with MS on muscle strength, aerobic capacity, walking performance, fatigue, gait, balance and quality of life.¹⁸

Q: Are there any other specialists I should look into, like a nutritionist or physical therapist?

 Pregnant women with MS should be managed in collaboration with appropriate HCPs.³ This can include a nutritionist or physical therapist as needed, based on the patient.

Q: What should I expect when I give birth?

- Although not all reports concur, there are probably no significant differences in gestational age, birth weight, length of birth hospitalisation, and frequency of assisted vaginal delivery or caesarean section between women with MS and the general population.¹⁹
- In a majority of cases, having MS does not guide obstetric management; there may be slightly increased risks of induced, operative, or assisted delivery. Delivery methods do not appear to influence MS disease course.³

• The only possible exception where MS may guide obstetric management is in patients with relevant neuromuscular weakness, spasticity and fatigue, in which case a caesarean section may be needed.

Q: What type of anaesthesia is safe for a person with MS?

Any anaesthetic choice is acceptable.²⁰

Q: Should I breastfeed?

- A recent very large analysis comparing healthy siblings (one breastfed, the other bottle fed), did not confirm any advantage of breastfeeding over using formula.²¹ Women with MS should be told it is acceptable to choose not to breastfeed.⁵
- The majority of studies have shown that breastfeeding has no effect on MS course, although its role is still controversial and a few recent studies suggest a potential protective role.¹
- Individualised counselling is recommended regarding whether a mother should breastfeed her child or resume or initiate DMTs immediately post-partum, because their relative protective effects on relapse risk are unknown.³

Q: Will I be able to stay on medication if I breastfeed?

- For women taking MS treatments, breastfeeding is not recommended.⁴
- Mothers should start DMTs only after complete weaning of their infant.³

Q: What should I expect during the post-partum stage?

- Typically, the major post-partum issue is whether to breastfeed, or to start, or restart, a DMT.⁵
- The rate of relapses has been shown to be increased in the first 3 months after pregnancy.²²
- Fatigue may take a bit more managing as a new mother with MS, since tiredness is also a common symptom of MS.¹⁶

Q: What is my risk of having a relapse during the postpartum period?

- Relapses are fewer during pregnancy, but increase during the postpartum period; this conclusion is supported by a meta-analysis of 13 studies including 1,221 pregnancies, showing that mean relapse rate decreased from 0.43 to 0.18 (p<0.0001) during pregnancy, and increased to 0.70 in the post-partum period (p<0.0001).¹
- The multicentric, prospective pregnancy in MS study showed the mean annualised relapse rate was 0.7 in the year before pregnancy, decreased by about 70% during late pregnancy (to 0.5 in the first trimester, 0.6 in the second trimester, and 0.2 in the third trimester), but by contrast it increased to 1.2 in the first trimester after delivery, returning to pre-pregnancy level by the end of the 12-month period after delivery.¹
- A more recent study utilising the international MSBase registry, showed that the annualised relapse rate in the pre-conception period was found to be the strongest predictor of early post-partum relapse, suggesting that minimising relapse frequency prior to conception may lead to better early post-partum outcomes.²³

Finally, patients may ask about where to find more information on the topic of family planning, as well as any educational seminars and services that may be available for women with MS who are planning a family. It can be helpful to refer them to local patient advocacy group websites or provide information on any other services/resources you are aware of in your area. \square

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Multiple Sclerosis and Family Planning – Patient Educational Materials

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Family planning questions for women with multiple sclerosis to ask their healthcare team

MS is more prevalent among women of childbearing age than any other age group, with onset usually occurring at the age of 20–40 years.⁴ Whether you are ready to start a family now or think it may be in your future, it is important to discuss these questions with your healthcare team when you are diagnosed so you can best prepare for your future. Many women go on to have children after an MS diagnosis and are just as likely to conceive and have healthy children as anyone else.⁶

Staying informed and talking with your neurologist/MS healthcare team is an important part of managing your MS. If you are thinking about planning a family, it is also important to involve your obstetrician/gynaecologist. It may also be helpful to find a therapist or counsellor that is knowledgeable about MS for discussions that go beyond your medical visits. The goal of these questions is to help you engage in deeper and more meaningful conversations about your future with your full healthcare team.

Below are suggested questions to ask your healthcare providers as early in your MS journey as possible, to facilitate discussions that will set you up to better navigate the road ahead.

• If I would like to get pregnant someday (but not in the near future), what should I start thinking about now?

- If I want to get pregnant now/in the very near future, what should I start doing now to plan for that?
- Does wanting a family impact my treatment plan?
- Do I need to use contraception while I am on MS medication?
- Do I need to stop treatment if I want to get pregnant?
- Are any symptoms worsened during pregnancy?
- Will I be able to stay on my medication while I am trying to conceive?
- Will I be able to stay on my medication while I am pregnant?
- · Will I be able to stay on medication if I breastfeed?
- What type of anaesthesia is safe for a person with MS?
- What should I expect when I give birth?
- What should I expect during the post-partum stage?
- What is my risk of having a relapse during the post-partum period?
- What is my child's risk of developing MS?
- Can I take pre-natal vitamins?
- Can I remain active/exercise during pregnancy?
- Are there any other specialists I should look into, such as nutritionists or physical therapists?
- Where can I find more information on family planning with MS?
- Are you aware of any educational seminars or services for women with MS who are planning a family, or for new mothers?

Multiple sclerosis and family planning fact sheet

MS is a chronic, unpredictable and progressive disease of the central nervous system (CNS), which is made up of the brain and spinal cord.²⁴ In MS, the loss of myelin, which is a sheath that forms around the nerves, leads to disruptions in the transmission of electrical impulses to and from the brain, causing MS symptoms.²⁵ MS can cause a variety of neurological symptoms, which for many people can flare up and then subside over the course of days, months, or even years.

The symptoms experienced by MS patients can vary significantly, but the most common symptoms experienced include some combination of fatigue, vision problems, numbness and tingling, muscle spasms, stiffness and weakness, mobility problems, pain, problems with thinking, learning and planning, depression and anxiety, sexual problems, bladder problems, bowel problems,²⁴ and speech and swallowing difficulties.²⁷

Know the facts about multiple sclerosis

Types of multiple sclerosis

MS affects everyone differently, but there are three main types of MS: RMS, primary progressive multiple sclerosis (PPMS) and secondary progressive multiple sclerosis (SPMS).²⁸

Relapsing forms of MS are the most common type of MS. A person with RMS experiences attacks of worsening neurological functioning (also called relapses or exacerbations), followed by periods of remission in which partial or complete recovery occurs.²⁹

At onset, approximately 80% of people with MS have RMS, and >65% of these develop SPMS later on in the course of the disease. The remaining $\sim 20\%$ have PPMS.³⁰

SPMS is identified by a sustained build-up of disability independent of relapse, and can be difficult to diagnose. However, people's experience of SPMS can vary widely.³¹ With PPMS, symptoms gradually get worse over time, rather than appearing as sudden attacks (relapses).³²

Prevalence

There are around 2,300,000 people living with MS worldwide and an estimated 500,000 to 700,000 people in Europe with the condition.³³ Although MS is found in all parts of the world, its prevalence varies greatly, being highest in North America and Europe, and lowest in sub-Saharan Africa and East Asia.²⁴

What causes multiple sclerosis?

The cause of MS is unknown. It has, however, been suggested that MS is likely to be caused by a mix of genetic, environmental and/or lifestyle factors.³⁵

Demographic

MS affects more women than men, and it is estimated that roughly between two and three women have MS for every man with the condition.³⁶

Know the facts about multiple sclerosis and pregnancy

Multiple sclerosis and family planning

MS is more prevalent among women of childbearing age than any other age group, with onset usually at the age of 20–40 years.⁴ Many women go on to have children after diagnosis.⁶ Women with MS are just as likely to conceive and have healthy children as anyone else.¹

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Fertility

MS is not known to significantly affect fertility. Women with MS who are trying to conceive should speak with their healthcare team to discuss any concerns. It is also important to know that 43% of pregnancies in Europe are unintended. Women with MS who think they may have become pregnant unexpectedly should speak to a healthcare practitioner right away, so they can best manage their pregnancy and their MS.

Pregnancy and delivery

There is a great amount of research to show that women with MS go through healthy pregnancies just like anyone else. 11 For example, babies born to mothers with MS do not have a significantly different average gestational age or birth weight compared to mothers without MS. 39 Also, pregnancy does not speed up or worsen MS – in fact, researchers have discovered that pregnancy can have beneficial effects on the mother's health during pregnancy. 11

Risk of passing on multiple sclerosis

MS is not considered to be hereditary, and children of a parent with MS have a 4.0% risk of developing the condition themselves, which is the same rate as the frequency of birth defects in the general population. The general population has a 0.2% risk of developing MS.¹¹

Relapses

Research in thousands of women has shown that women with MS tend to experience fewer relapses during pregnancy, particularly in the third trimester.¹¹ However, relapse rates often increase within the first 3 months after birth.¹¹

Fatigue

Fatigue is a common symptom of MS, ¹⁶ so as a new mother with MS, tiredness may take a bit more managing. Women with MS who are new mothers may want to seek support around the first few months if possible, and get plenty of rest.

MS medication during pregnancy

None of the MS treatments are approved for use during pregnancy.²³ However, for pregnant women with severe or highly active MS, the benefit of certain treatments may outweigh the unknown risk to the foetus, and this is a decision to be made by the treating physician.³⁷

Breastfeeding

For women taking MS treatments, breastfeeding is not recommended,⁴ but this should be discussed with a healthcare practitioner.⁶

Family planning tips for women with multiple sclerosis

Starting a family can be a big step for many women. Being diagnosed with MS may leave you with questions and concerns about becoming pregnant and planning for a family.

Many women with MS go on to become mothers after their diagnosis. Speaking to your healthcare team as early as possible about your personal thoughts on this matter can help you manage your MS and your journey through parenthood.

In addition, there are many proactive strategies and tips women can incorporate into their current lifestyle to help support them through their journey. The following tips offer guidance on how to build a healthy and balanced lifestyle if you are planning a family.

- Whether you are ready to start a family now or sometime in the future, it is important to share your plans with your healthcare team as soon as possible, so they can work with you to manage your symptoms and disease course as you try to conceive, and while you are pregnant or breastfeeding.⁴⁰
- When speaking with your healthcare team about planning for a family, make sure to consider every stage – from trying to conceive through pregnancy, the post-partum period and breastfeeding. The more knowledge you have in advance, the better prepared you will be to navigate this exciting time in your life.⁴⁰
- If you don't have one already, take the time to build a solid support network of reliable friends and family on whom you are comfortable calling for support. While pregnancy and childbearing are wonderful stages in life, they can also be very physically and emotionally demanding.⁴⁰

- Although pregnancy has been shown to have beneficial effects on MS, some women may find themselves experiencing a relapse within the first 3 months after birth. Consider having a conversation with your partner about any extra support you may need around that time, or asking for help from family and friends. The key thing is to start early once you have decided to have a baby, start thinking about how you can make the period immediately after birth as easy as possible for yourself.²³
- Some MS symptoms can become worse during pregnancy. Talk to your obstetrician/gynaecologist, MS nurse and/or midwife about the impact of pregnancy on your body, to create an individualised plan.⁴⁰
- Pregnant women with MS are more prone to urinary tract infections. Drinking water and getting monthly urine tests can help prevent this from happening.¹
- A healthy diet, adequate rest and exercise are all essential to feeling one's best. A healthy diet includes eating foods that are high in vitamin D, which may have important effects on the immune system and help regulate cell growth. Vitamin D can be found in almond milk, egg yolks and oatmeal.⁴¹ The National Institute for Health and Care Excellence (NICE) recommends daily supplementation of 400 units (10 mcg).⁴²
- Depression is more common in people with MS than in the general population. Track your feelings and mood changes and be sure to report them to your HCP to help manage depression.⁴³
- Put together a plan to help you manage stressful situations, such as what to do if you are feeling ill and who to contact when you need support.
- Consider joining a support group to share experiences with other women and/or new mothers who have MS. It is an opportunity to learn new tips, as well as to enjoy sharing experiences. Talking through your concerns can help manage your stress. □

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