CHESS
Children's Early Self-Care Support

CHESS is a large national research study. It focuses on young children aged 12 months to 4 years 6 months. It evaluates the impact of NHS therapy on children's Development, personal care, and independence – as well as on parent wellbeing.

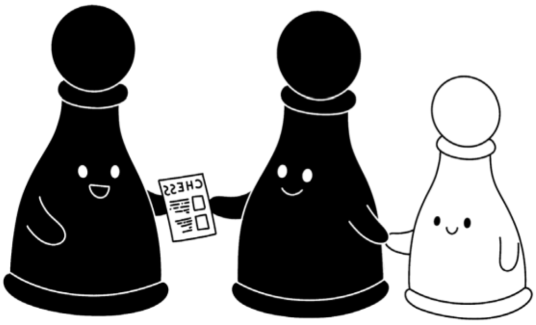
Join our vital research to improve NHS therapy services for young children.

WHY ARE WE INVITING YOU?

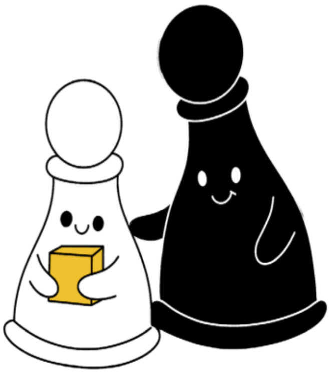
We are looking for 24 parents from your local NHS service to take part.

You have been chosen because:

- Your child is between age 12 months to 4 years and 6 months.
- We want to include a mix of children with different skills, strengths and difficulties.
- We want to include a mix of families from different backgrounds and local areas.



WHY ARE WE DOING THIS RESEARCH?



We want to help all young children reach their full potential. If you decide to take part in this research, you will be contributing vital information to improve NHS therapy for young children.

Parents and children have told us they want better support for young children's personal care and independence – for young children to do things for themselves and to have a say in things that affect them.

Early years is one of the most important times for laying strong foundations for the future. Parents want NHS therapists to pay more attention to personal care in young children, including with children with complex needs.

WHO HAS SHAPED THIS RESEARCH?

This research has been designed together by parents, young people, experienced therapists, and independent researchers.

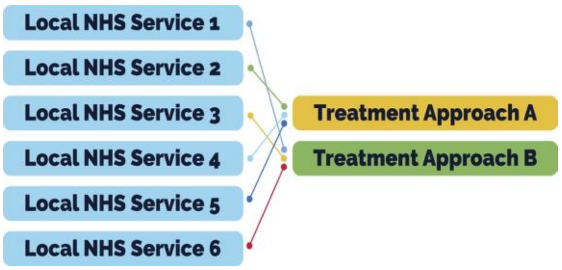
Parents and young people decided which outcomes the research should focus on. They also designed the CHESS therapy approach.

The research plan was reviewed for funding by an independent national panel at the National Institute for Health and Care Research, and by an NHS Research Ethics Committee (Ref: 24/NE/0162, IRAS 331267).

WHAT WILL HAPPEN IN CHESS RESEARCH?

NHS SERVICES ARE TAKING PART

40 NHS therapy services across England, Scotland, Wales and Northern Ireland are taking part, including your local NHS. They are working with parent organisations and independent researchers. In the coming weeks, a computer will assign your local NHS service to provide one of two treatment approaches. All therapist in the local service will then use that approach, and all children in the service will receive that approach. Importantly, this does not involve randomly allocating individual children or parents to treatments.



SEEKING TO IMPROVE TREATMENTS

The information from parents and services will help us to compare the benefits of the two therapy approaches. Once we know the benefits, this information can be used to help improve treatments for young children across the country.

PARENTS PROVIDING INFORMATION

The most important measure of therapy is whether it helps the child in everyday life. We invite you to complete questionnaires and share information, confidentially, to help us assess this.

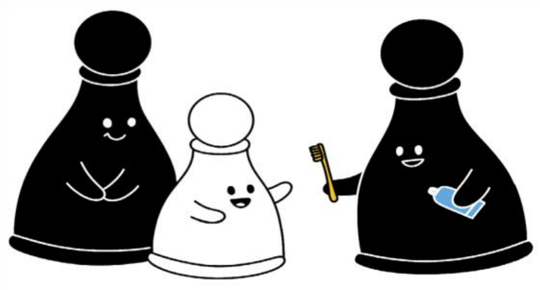
If you take part, we ask you to:

- Answer questionnaires online or over the phone. We ask you to do this in the next couple of weeks, and then again in 6, 9 and 12 months' time. A full, set each, time takes from 15 to 60 minutes to complete.
- Give your permission for the NHS service to share basic health information about your child with us, confidentially (please see FAQs).

We may also later invite you to participate in additional activities, but this is entirely optional.

You do not have to take part and your decision will have no impact on your child's therapy.

We have included more information in the Frequently Asked Questions (FAQs).



WHAT DO I NEED TO DO NEXT?

🌐 **https://ace.abdn.ac.uk/CHESS/**

☎ **01224 438156**

We have put together some common questions and answers about the CHESS research. Please take a look at them.

If you would like to take part, or know more, please text or call us on 0000000 0000 or email us at

CHESS@abdn.ac.uk

You can also reply using the return slip and the enclosed envelope (postage paid!). We can be contacted at any time, and if we miss you we will call you back.

Frequently Asked Questions (FAQs)

We have included more information about the CHESS research in this pack.

The information in this pack is detailed, and we have sought it to be comprehensive. You do not have to read it all.

You can choose to read the questions and answers that are relevant to you. You can keep this information, and come back to it.

If easier, you can also just contact us:

By phone: 01224 438156

By email: chess@abdn.ac.uk

You can also access this information online: >>add CHESS website<<

Or, you can use the QR code, below:

>>add QR code<<

If you would like this information in a different language to English, please contact us.

Frequently Asked Questions (FAQs)

We have included more information about the CHESS research in this pack.

What is CHESS?

CHESS is a major, national research study. It aims to find better ways to help young children to grow their independence in everyday self-care activities, like using the toilet, having a bath, and getting dressed.

It involves therapists across 40 NHS centres, comparing a therapy called Children's Early Self-care Support (CHESS) with the support that therapy teams currently provide. CHESS is a study of 'clusters' – this means that some of the NHS centres taking part will provide the CHESS therapy and some of the NHS centres will provide standard therapy. At each individual centre, all children and families will receive the same kind of support.

Why is the CHESS study happening?

Young people who have received therapy in the past, parents of young children receiving therapy, and therapists have asked us to make therapy better. Together, they have agreed that we must work to better support children who need help with independence and everyday activities (e.g. eating and drinking, getting dressed, getting around, sleeping).

We know that it is really important to help young children to develop independence as early as possible. At the moment, we do not know how best to help. There is currently little evidence and no national guidelines.

What is the research aim, and what is the study design?

The aim is to investigate whether CHESS is better than the usual support provided by therapists. We do this by comparing treatment systems. In CHESS, we compare one 'system' of supporting children (called CHESS or 'CHildren's Early Self-care Support', for long) with the current 'system' – the usual self-care support.

We will ask 40 NHS organisations to join the study. Half the organisations will use CHESS and half will use their usual self-care support. Across the 40 organisations, we will ask 960 parents to share information with us, about their children's self-care, health, and quality of life, as well as about the parents' health and wellbeing. We will also ask how much parents and services spend on accessing and providing support. We will compare the services several months after the start of the CHESS study to see whether CHESS improves self-care and is a sensible use of public money. To help the study run smoothly and explore people's experiences of CHESS, we will do interviews and focus groups with parents and therapists in some services. We will closely monitor whether CHESS has any potential risks or harms for children or parents.

Once we have done the study, we will be able to help therapists, and NHS funders, to plan and use treatments that work best in helping children and families and that are the best use of healthcare resources.

Who is running the study?

The research is being carried out by a group of experienced healthcare professionals and researchers from Newcastle University, University of Exeter, Sheffield Children's NHS Foundation Trust, Bangor University, London School of Hygiene and Tropical Medicine, Northumbria University and Pennine Care NHS Foundation Trust and the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen. This study is sponsored by the Sheffield Children's NHS Foundation Trust who have overall responsibility for the management of the study.

Who is funding the study?

The study is funded by The National Institute for Health and Care Research (NIHR), Health Technology Assessment Programme (project number NIHR156487). There is a steering group who meet regularly to advise the research team which includes experienced researchers, health and social care professionals and service users.

What does this mean for my child's treatment?

All Your children at your local NHS will receive the same treatment approach. as all other children in your local centre. This will either be the current therapy care or the CHESS therapy. We do not currently know which, if either, of these therapy approaches is better.

There is no treatment at random for individuals in CHESS. Your child will receive the same treatment approach regardless of your decision to take part in the data collection part of the CHESS study or not. The treatment approach that your child will receive will always be tailored to your child's needs by their therapist.

In the CHESS study, the focus is on comparing 'clusters', meaning NHS centres. In CHESS, some centres will be trained to provide 'CHildren's Early Self-care Support' (CHESS), while other centres will continue with their current approach. The approach provided by any one centre is decided, at the start of the study, by "a toss of a coin" (using a computer to allocate, by a random chance, centres to either provide CHESS or current care). This "toss of a coin" is a well-established approach in research, to compare treatments when we don't know which one is best. This is called randomisation.

Once the therapy approach for your NHS centre has been set, all the therapists in the centre will use that approach with all children – including your child. Your decision to take part in the study will not change the therapy approach used by your local NHS centre and team.

Why do you need information from me?

Comparing the centres is only possible if we receive information from families about the impact that the therapy had. The information we are asking you to share with us, through the questionnaires, is essential for finding out which therapy approach works best. Without the information from questionnaires, the comparison is not possible.

Why am I being invited to take part in the data collection part of the CHESS study?

We are looking for 24 parents from your local NHS service to take part. You have been chosen selected because:

- Your child will be seen by a participating therapy service during the research period.
- Your child is within the age range for this research.
- We want to include a mix of children with different skills, strengths and difficulties.
- We want to include a mix of families from different backgrounds and local areas.

How long does the CHESS research study run for?

If you decide to take part, your involvement will be for 12 months. The overall CHESS study will run for 4 years and aims to recruit 960 young children (aged from 12 months to 4 years and 6 months old) and their families from 40 NHS centres across the UK.

Do I have to take part in CHESS?

No. You are free to choose, and your decision will not impact your child’s care or the support you will receive. Taking part in the CHESS data collection is optional. Your decision will have no impact on your child’s therapy, or the support you will receive.

If I follow up on the invitation, what will happen next?

We will contact you to discuss the CHESS study more. We will talk about the study with you, help you read or listen to the information provided, and invite you to ask any questions you have. If you would like another person present when speaking to the research team, please let us know and this can be arranged. We can also arrange an interpreter if needed.

If I decide to take part, what will that involve for me?

1. Consent: First you will be asked to give your formal agreement (‘consent’) to participate in this research.
2. Questionnaires: We will then ask you will be asked to fill in questionnaires about you and your child. We text or email links to these questionnaires to you. There are several ways for you to then complete them:

- Online: You can log in and complete them online, where and when it suits you.
- By phone: You can also choose to do it over the phone with a member of the research team.
- In person: Or we can visit you at home if you feel you need additional support to complete the questionnaires.

If you would like another person present when speaking to the researcher, please let us know and this can be arranged. We can also arrange an interpreter if needed.

A full list of the questionnaires that we ask you to complete:

Topic	**What is it about?**	**When, how long, where?**
Your basic details	You and/or your child's date of birth, post code, ethnic background and some health information. We are collecting this to make sure we include a diverse group of people, so that our results reflect the whole of the UK. Your answers really help us describe the range of people who are taking part in the study.	We ask this at the start of the study only. This takes around 10 minutes, and you can do it online, over the post, or over the phone.
The main research outcomes	A set of questionnaires that asks about your child's personal care, development, and wellbeing – and also asks about your health and wellbeing. Your answers are really important as they help us understand if there is any change over time.	We ask this at the start of the study, 6 months later, and 12 months later. This takes around 60 minutes, and you can do it online or over the phone.
Time and Travel	We will ask you to fill in a time and travel questionnaire about how much it costs you to access healthcare for your child. This helps us understand the burden that NHS care puts on you and your family.	We ask this 9 months after the start of the study, and only once. This takes around 20 minutes, and can be completed by post, online, or over the phone.

One of the questionnaires (completed at baseline, 6-months and 12-months) can only be completed through a secure web-based system maintained by the owner of the questionnaire – a company called Pearson Clinical. In order to complete this questionnaire, we will ask for your permission to share your child's date of birth and sex with Pearson Clinical. This means that the questionnaire will only include questions that are relevant to your child. We will not provide Pearson with your name, your child's name or your contact details.

If I decide to take part, what information will the NHS service share about us?

Your local NHS therapy team will share, confidentially, some basic information about your child with the research team: their name, date of birth, any medical diagnoses they may have, and therapy treatments they have had and receive during the study period.

This information will be shared through a secure online data portal, and will be kept secure at University of Aberdeen. The information will be transferred and stored in a non-identifiable form that uses a numeric code to label the data, rather than using your child's name. This is to keep your child's information secure.

How will my decision to take part or not affect my child's therapy?

Your decision will not affect your child's therapy. Whether or not you take part, your child will receive the same care and support.

If you choose to take part:

- You will attend your child's therapy appointments as scheduled,
- The study will not require extra visits, and
- your child will receive the same therapy approach as they would if you did not take part.

If you chose not to take part, your child will still receive the same therapy approach. The only difference is that you will not be asked to complete questionnaires, and your local team will not share information about your child with the research team.

What should I do if I am not sure about taking part?

Please ask us if there is anything that is not clear or if you want to know more. You may want to discuss the CHESS study with your family and friends or health care professionals working with your child.

If you would like to know more, have any questions, or would like to get involved, please text or call us on 0000 000 0000 or email us at CHESS@abdn.ac.uk. You can also send us your details in the enclosed envelope (postage paid) – and we will call you <<remove for online version>>.

What if I want to later withdraw from the CHESS study?

You can stop being part of the study at any time, without giving a reason.

If you withdraw, we will keep the information you have already provided. Withdrawal will not affect the care your child is receiving now or in the future. Your child will continue to receive the same care as the other children within your local centre.

If you stop taking part in the study, we would like to continue collecting information about your child's health from your local NHS team, while the CHESS research is ongoing. If you do not want this to happen, tell us and we will stop.

If during the study you lose capacity to take part, you and your child will be withdrawn from the study, but we will keep the information that you have already provided. Any data we do have will remain confidential and will not be used for any other purpose.

If you would like to withdraw, you can do this by contacting the CHESS study office at CHESS@abdn.ac.uk or by calling us on XXXXXX.

If I agree to take part, will you later ask me to do more?

When you agree to take part, we will ask you whether or not you would like to be approached for additional components. If you agree, you may be asked to participate in other, optional activities.

For example, an interview to understand you and your families experiences. If you are asked, you do not have to agree. This is optional, and you can decide later.

If your child is taking part in the data collection part of the CHESS study, and you have chosen to accept invitations to other studies, you may be invited to:

- Take part in interviews. We would like to explore your experiences of being involved, including: why you decided to take part, what you feel about your child's care.
- Take part in an observation. We would like to observe specific appointments (e.g. clinic appointments, home visit) to better understand how care is delivered across the study.
- Let us record the conversation you had with the study team about taking part in CHESS. We would like to understand the kind of questions people have about the study. We can use this information to make sure that people get the right information to make their decision and are supported in the best possible way.
- Take part in interviews and complete an additional health economics questionnaire . We would like to explore what is important to you and your child in early years self-care support services.
- Fill in the 6-month questionnaires again. We would like to ask some parents to complete the 6-month questionnaires again to explore the reliability of these questions for parents with a child in this age group.
- Longer term follow up. We would like to seek funding to follow up you and your child in the longer term (beyond 12 months).
- Other relevant research. We may want to contact you to ask if you would be interested in any other relevant research.

If you decide not to take part in the CHESS study you can still decide to:

- Take part in an interview. We would like to explore your experiences of being invited to the study and explore reasons why you decided not to take part.
- Let us record the conversation you had with the study team about taking part in the CHESS study. We would like to understand the kinds of questions people have about the study. We can use this information to make sure that people get the right information to make their decision and are supported in the best possible way.

Please note that places on these optional extra studies are limited. We are unable to work with everyone who is interested and not everyone who indicates interest will receive further information about taking part in these studies.

What will happen to the results of the study?

We will share the results will all parents who take part (unless you tell us that you do not wish to know), as well as all the therapy teams. We will also actively share them with decision makers, and NHS funders. We will make easy to understand summaries openly available.

We also intend to publish the results in scientific journals, conferences, and newsletters. You and your child will not be identified in any report or publication.

What are the benefits of taking part?

We are not certain that you or your child will gain any direct benefit from taking part. By taking part, you will be helping us learn more about how to better support therapy services for young children.

The results of this study will help NHS services to plan more effective therapy in the future, benefitting children and families nationwide. We cannot make claims that you or your child will gain any direct benefit from taking part.

What are the disadvantages and risks of taking part?

We do not think that there are any risks to you or your child in taking part.

We understand that completing the questionnaires will require some of your time. We have worked with parents to make this time commitment as little, and as flexible, as possible.

Collecting information from parents is the only way to find out if the therapy your child receives is helpful or not – and without this information we cannot get the answers to make treatments better.

Are there expenses or payments?

There are no expenses or payments for taking part in this study.

How do you protect my information?

All data collected is subject to the UK's data protection laws.

Throughout the research, to safeguard your rights, we will use the minimum personally identifiable information possible. We are required to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Sheffield Children's NHS Foundation Trust is the Sponsor for the study and takes overall responsibility for the management of the study. Sheffield Children's NHS Foundation Trust is the data controller for this study and is responsible for looking after your information, using it properly and complying with your rights. You can find more about this at https://www.sheffieldchildrens.nhs.uk/your-information/ or by contacting us at the address below.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information which is collected about you and your child for the purpose of this research study will be handled in strict confidence and securely stored by the University of Aberdeen, Bangor University, Newcastle University, Northumbria University (where appropriate). All information that is collected about you and your child during the course of the research will be kept strictly confidential. The data collected from the study will be stored on secure University of Aberdeen, Bangor University, Newcastle University, Northumbria University (where appropriate) servers.

How will you use the information about me and my child?

We will need to use information from you and your child for this research project. This information will include:

- Name and contact details of you and your child
- Date of birth and NHS number of your child
- Diagnoses of your child

- Ethnicity and sociodemographic information of you and your child

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. Anonymised direct quotations from you which may be included in the study reports, publications and oral presentations. We will write our reports in a way that no-one can work out that you or your child took part in the study.

- The local research team at the therapy service that your child was recruited in will have access to your information. They will use your name and contact details to contact you about the study, to make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study.

- The CHESS study team who are based at Aberdeen, Bangor, Newcastle and Northumbria will have access to your information to contact you about the study, for example to send you the questionnaires, and for quality control purposes, such as auditing the data collection process. All electronic data collected for the purpose of the research study will be confidentially and securely stored on computer servers maintained by the University of Aberdeen, Northumbria University, Newcastle University, Bangor University or <<XXXX>>. The local research team will pass information collected from you and information collected from your child's medical records to the study team.

- The statistical analysis of the study is being conducted at the University of Aberdeen. To maintain confidentiality, this team will only analyse anonymous data. (Anonymous data does not include names or addresses, and it is not possible to identify individual participants from anonymous data).

- The health economic analysis of this study is being conducted by Bangor University. To maintain confidentiality, this team will only analyse anonymous data.

- The process evaluation data analysis is being conducted by Northumbria University. To maintain confidentiality, this team will only analyse anonymous data.

- Other individuals from the Sheffield Children's NHS Foundation Trust, the Research and Development department of your local therapy service and the Regulatory Authorities may look at your child's medical records and data collected for the study, to check that the study is being carried out correctly and to check the accuracy of the research study. All will have a duty of confidentiality to you and your child as research participants.

- Your child's date of birth and sex will be shared with Pearson Clinical, in order to administer one of the questionnaires for the study. This means that the questionnaire will only include questions that are relevant to your child. Your name, your child's name and your contact details will not be shared.

- Other researchers may wish to access anonymous data from this study for future research. If this is the case, they would be expected to follow legal, data protection and ethical guidelines. It will not be possible to identify you or your child from this data. The information will only be used for the purpose of health and care research and cannot be used to contact you or affect your care.

Your rights to access, change or move you or your child's information are limited, as we need to manage you and your child's information in specific ways in order for the research to be reliable and accurate.

How long will you keep the data?

All information which is collected about you during the research, including identifiable data, will be held securely for 10 years after the study has finished in accordance with Sponsor requirements and data legislation. After this time your data will be disposed of securely.

Where can I find out more about how my information will be used?

You can find out more about how we will use your information:

- At www.hra.nhs.uk/information-about-patients/
- By sending an email to chess@abdn.ac.uk or by calling us on 01224 438156
- By contacting the Data Protection Officer at scn-tr.dataprotection@nhs.net
- The Health Research Authority provides general information about how research information is used for participants on their webpage (www.hra.nhs.uk/information-about-patients/)

If you are not able to access the web links above please contact us and we will send you this information.

Who has reviewed the ethics of this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your and your child's interests. This study has been reviewed and given favourable opinion by Newcastle and North Tyneside 1 Ethics Committee (ref. no. 24/NE/0162).

The Newcastle and North Tyneside 1 Ethics Committee (ref. no. 24/NE/0162), which has responsibility for reviewing all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. The Research and Development Department of your local hospital has also reviewed and approved the study.

What happens when the research study stops?

If the study is stopped earlier than expected for any reason, we will tell you and arrange continuing care for your child.

At the end of the study, all children and their parents will continue to receive self-care support from their local clinical team.

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the CHESS Study Office will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

What if there is a problem?

If you have a question or concern about the study, you can ask to speak with the local research team who will do their best to answer your questions. Contact details for your local research team can be found at the end of this leaflet.

You may also contact the CHESS study clinical team 24hr telephone line on <<XXXXXXXX>> or Niina.Kolehmainen@newcastle.ac.uk.

If you have any questions or concerns about the questionnaires, please contact the CHESS study office at CHESS@abdn.ac.uk or 01224 438156.

If you wish to complain formally or have any concerns about any aspects of the way you or your child have been approached or treated during this study, you can do this through the normal NHS Complaints Procedure. Details can be obtained from your therapy service.

If your complaint is in relation to how your data is being used or processed you can contact the Information Commissioners Office. All of these contact details are given at the end of this document.

We do not expect any harm to come to you or your child by taking part in this study. If something does go wrong, and you believe that you or your child are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsor of this study, Sheffield Children's Foundation Trust.

If your child is harmed due to someone's negligence, then as a patient of the NHS, you may have grounds for legal action. You may have to pay for your legal costs yourself.

Thank you

Thank you for taking the time to consider participation in the CHESS research. We hope that this information has been helpful in helping you to decide if you would like to participate in the CHESS study.

Please ask us if you have questions or would like more information about the study.

Further information and contact details

If you have any questions or would like any more information, please contact:

Contact Us

CHESS Study Office

University of Aberdeen

Tel: 01224 438156

Email: chess@abdn.ac.uk

[Local PI/Contact details]

NAME

Tel: [phone number]

Email: [email address]

Professor Niina Kolehmainen

CHESS Chief Investigator

Tel: [phone number]

Email: Niina.Kolehmainen@newcastle.ac.uk

Sheffield Children's NHS Foundation Trust

Study Sponsor

Tel: [phone number]

Email: [email address]

Data Protection Officer

<<NAME>>

Tel: [phone number]

Email: scn-tr.dataprotection@nhs.net

[Local complaints details]

NAME

Tel: [phone number]

Email: [email address]

Information Commissioner's Office (ICO)

For concerns about how your data is being used or processed please contact the ICO https://ico.org.uk/concerns/