Informed Consent Cover Page for FDAAA consent posting:

Official Title: *A Study to Evaluate the Effects of fixed dose Flavonoid Isoquercetin on thrombo inflammatory biomarkers in subjects with stable Sickle Cell Disease*

NCT Number: NCT04514510

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PRINCIPAL INVESTIGATOR: Arun Shet, MD, PhD

STUDY TITLE: A Study to Evaluate the Effects of fixed dose Flavonoid Isoquercetin on thrombo-inflammatory biomarkers in subjects with stable Sickle Cell Disease

STUDY SITE: NIH Clinical Trial Center

Cohort: Affected patient

Consent Version: October 27, 2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

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KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being invited participate in this study because you have sickle cell disease (SCD).

Patients with SCD have an increased chance for developing blood clots. The purpose of this research is to study the effects of a dietary supplement, Isoquercetin in patients with sickle cell disease, and see if there is an association between taking this supplement and a decrease in the levels of inflammation and clotting in your blood. Isoquercetin is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat SCD. However, the FDA has given us permission to use Isoquercetin in this study.

In this study, you will be assigned to 1 of 2 groups to receive either the study supplement (Isoquercetin), or a placebo (sugar pill). Neither you or the study team will know which group you are assigned to. This process is called randomization, and is similar to the flip of a coin. We will ask you to take Isoquercetin or placebo capsules by mouth every day for 4 weeks. We will collect blood and look for specific changes in inflammation and blood clotting. We are looking for a relationship between taking the supplement and a decrease in levels of inflammation and clotting.

You are invited to take part in this study because you have sickle cell disease, are in your usual state of health, i.e., "steady-state" and have not experienced a pain crisis within the last 60 days. If you are taking hydroxyurea, your dose has not changed within the past 90 days.

Your participation in the study may last up to 12 weeks. Your initial visit will determine if you are eligible to participate in the study. At this visit you will have blood work, we will review your medical history and medications, and have a physical exam. Once we determine that you are eligible, we will ask you to participate in 2 study visits over a 4-week period. We may ask you to return for an additional visit at the end of the study if you experience any side effects.

The general risks associated with this study pertain to the dietary supplement, Isoquercetin and having a blood draw. Isoquercetin is very similar to quercetin which is a naturally occurring substance in fruits and vegetables, especially apples and onions. Isoquercetin, has been used in clinical trials with minimal side effects in patients; we will discuss these side effects further in this consent document. The risks associated with the blood draws are minimal and involve pain, mild bruising, and possible infection at the site where the blood is taken.

You will be compensated for your time and inconvenience for participating in this research study.

You can discuss this study with your doctor to see if there are other alternative studies that you can participate in if you decide not to participate in this one.

You may or may not benefit from being in this study. If you are assigned to receive Isoquercetin, your risks of developing a blood clot while in the study may be reduced. Also, taking part in this study could help others in the future.

The remaining document will now describe more about the research study. This information should be considered before you make your choice. Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

This is a research study. The purpose of this research study is to see how the dietary supplement Isoquercertin works in people with sickle cell disease (SCD). We are looking for a relationship between the supplement and a decrease in levels of inflammation and clotting.

We are asking you to join this research study because you have SCD, are in your usual state of health, i.e., "steady-state" and have not experienced an acute pain crisis in the last 60 days and if you are taking hydroxyurea, you have not changed your dose within the past 90 days.

Isoquercetin is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat SCD. This is why we are doing this research study; we want to see if there is a relationship between taking the supplement and a reduction in blood markers of inflammation and clotting in patients with SCD.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to come to the Clinical Center for 3 visits. Each visit will last about 2-3 hours.

- Visit #1: This is the **Screening Visit** where we will determine your eligibility to participate in this study. We will ask you to sign this consent document prior to any tests or procedures. This visit consists of reviewing your medical history, performing a physical exam, and blood work. If you are found to be a good fit for the study, meaning you are eligible, then we will invite you to participate in the visits listed below. If we find you are not eligible for this particular study, or you do not want to participate, your involvement will end with this visit.

- Visit #2: This is the **Baseline Visit**. If you are in a "steady state", meaning you have not had a pain crisis in the last 60 days and if treated with hydroxyurea, have not changed the dose in the last 90 days, you will have the following tests and procedures: clinical and research blood work, physical exam, and a review of your medications. We will ask you to participate in a peripheral arterial tonometry (Endo-Pat) exam and/or a near infrared spectroscopy (NIRS) oximetry measurement, however these tests are optional. At this visit, we will also "randomize" you to 1 of 2 treatment groups to receive Isoquercetin, or placebo (a sugar pill that has no active ingredient). Neither you nor the study team will know your group assignment.

  Taking the study supplement: You will take 4 capsules of 250 mg Isoquercetin or placebo all at once, by mouth every day for 4 weeks. This is about 1000 mg of Isoquercetin or placebo. The study supplement will be administered by a pill dispenser, which we will provide, that will help you remember to take the pills each day. You should take the capsules whole, with or without food. The capsules should be taken at a fixed time in the morning (e.g. 9:00AM) or at a time that is convenient for you. You can take them when you take your other medications, if you would like and if it helps you to remember to take the study supplement. If you miss a dose and it is more than 6 hours before the next dose

is due, then the dose can be taken. If a dose is missed and it is less than 6 hours before the dose is due, then the dose should be skipped.

We will provide you with a diary to record when you take the study supplement. While in the study, please try to maintain your current diet and activity level and not start any new diets or exercise programs. We will also ask you to not make any changes to your treatments for your SCD while you are in the study.

It is recommended that you take at least 1 mg of folic acid once a day while taking the study supplement. If you are not already taking folic acid a 30-day supply of 1 mg of folic acid will be prescribed for you to be taken once day.

- Visit #3: This is the **End of Study Visit**. At this visit we will perform the following: review any side effects you had while taking the study supplement, perform a physical exam, review medications, and collect blood for clinical and research labs. We will ask you to participate in a peripheral arterial tonometry (Endo-Pat) exam and or a near infrared spectroscopy (NIRS) test, however this test is optional. At this visit, you will return the pill dispenser with unused study supplement and the supplement diary.

- 24-hour Dietary Recall: You will be asked to complete three interviews with nutrition staff to collect information on what you ate and drank on the previous day. Interviews will be in person or conducted via telehealth and last for approximately 20-30 minutes. These interviews will be conducted at the Screening Visit, Baseline Visit and End Of Study Visit.

- Phone Call: About a month after your last study visit, a study team member will contact you to see if you are having any new or residual side effects from taking the study supplement. After the study is over, if you experienced any side effects, you may be invited for a follow up visit to the Clinical Center. At this visit you we will review your symptoms and may do blood tests, if needed.

- Extra Visits: If you are having side effects while you are taking the study supplement or symptoms from your SCD, we may ask that you return to the Clinical Center for an evaluation and possibly clinical blood work.

Optional Procedures under this study:

P***eripheral Arterial Tonometry (PAT) (ENDO-PAT 2000, Itamar Medical):***
ENDO-PAT will be performed at study visits 1& 2. It is an FDA-approved noninvasive technology that captures a beat-to-beat recording of the fluctuations in the amount of blood of the finger arterial pulse wave activity with a type of probes.

Near infrared spectroscopy (NIRS): Will be performed at study visits 1& 2. In this test, probes will be placed on your skin to measure oxygen levels, blood flow, and the make-up of your skin and muscle. A blood pressure cuff will be placed on your arm. The cuff will

be filled with air to briefly restrict the blood flow (for up to 5 minutes) in your arm and then released. You may also be asked to breathe at a certain rate or hold your breath for as long as you can during periodic measurements.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last from 8 to 12 weeks.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have up to 46 people participating in this study.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

Isoqucertin Related Risks

The most common side-effects from this supplement are nausea, acid reflux, constipation, diarrhea and rare reports of headache and mild tingling of the hands and feet. The study supplement might have a caffeine-like effect.

Blood collection:

There may be some discomfort on your arm when we collect your blood with a needle. There is a small chance that you will get a bruise, feel lightheaded, faint, or have an infection at the place where the needle was inserted. The amount of blood to be collected for the study is less than 6 tablespoons.

Peripheral Arterial Tonometry (optional):

This non-invasive test will examine the function and reaction of your blood vessels. A thimble-shaped cup will be placed on your finger that will place slight pressure on your finger and measure its blood flow. Simultaneously, a blood pressure cuff placed on your arm will be inflated to measure the effects on blood flow.

Near infrared spectroscopy (NIRS) (optional):
You may experience temporary discomfort related to the cuff squeezing, where we place probes, and from holding your breath.

What are the risks related to pregnancy?

If you are capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. We do not know if Isoqurecetin causes any risks to a fetus or unborn child. If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the treatment being studied that could

increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails while you are in the study. If you think or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. If you or your partner plan to become pregnant in the future, please wait at least 4 weeks after completing the course of this study supplement .

If you are a sexually active person with a partner capable of becoming pregnant, it is important that your partner not become pregnant during your participation in this study. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during your participation in this study, please contact the research team member identified at the top of this document as soon as possible. If you and your partner plan for your partner to become pregnant after your participation in this study, please discuss this with the study team.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You may or may not benefit from being in this study The main purpose of the study is to see if patients with SCD who take Isoqurecetin have a decrease in inflammation and clotting factors in their blood. If you are assigned to receive Isoquercetin, your risks of developing a blood clot while in the study may be reduced.

Are there any potential benefits to others that might result from the study?

Patients with SCD have an increased chance for developing blood clots. This study might help us learn if Isoqurecetin can help reduce inflammation and clotting markers in the blood of patients with SCD. More information is needed, including clinical trials to help prove if Isoqurecetin can actually help prevent blood clots in people with SCD.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

You do not have to participate in this study if you do not want to. You may withdraw from this study at any time. If you decide to withdraw from the study, we would like to keep your test results to properly analyze this research study. If you have concerns about this, please speak with members of your research team.

If you decide not to participate in this research study, other treatments or medications may be available for the treatment of SCD. There may also be other clinical research studies in which you may choose to participate. You may discuss these alternatives with your doctor and decide whether to participate in this study.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have

learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

You will be provided with the results of the standard clinical labs, but the results of our research studies will not be provided to you or your referring doctor.

EARLY WITHDRAWAL FROM THE STUDY

Discontinuing Participation:

- If you decide to stop participating in this study, you may request this by either informing the investigators or by writing to the research team to the address at the end of this consent (under Problems and Questions on last page of consent). You will not be asked for further information or samples.
- If we are unable to contact you or reach you.
- When the study has completed.

Discontinuing Treatment (You can still be part of the study and will be followed until end of study):

- If you experience specific sickle cell disease-related complications and/or you need a blood transfusion, you may be asked to discontinue treatment.
- If the study supplement affects the safety of your health or if the study doctor decides that it is in your best interest for you to be off the supplement.
- Pregnancy or unwillingness to use acceptable forms of contraception.

Research Subject's Rights: You are free to refuse to undergo any of these tests. You may withdraw from the study at any time. If you decide to participate and later change your mind, you are free to stop participation at any time. You will not be penalized or lose benefits to which you are otherwise entitled. Refusal to participate will not affect your legal rights or the quality of health care that you may receive at this center.

Explanation of Conditions for Early Withdrawal: If new previously undisclosed information emerges during the study that would exclude you from the study, the investigators looking after you will discuss these with you.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you.. We plan to store and use these

specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding sickle cell disease or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. These researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

Procedures	Compensation per procedure	Frequency	Total Compensation
Outpatient visit	$50	3	$150
Medical history and physical examination	$35	3	$105
Research blood draw	$60	2	$120
Labs	$50	2	$100
ENDO-PAT (optional)	$50	2	$100
NIRS (Near Infrared Spectroscopy (optional)	$50	2	$100
24-hour Dietary Recall	$15	3	$45
End of study phone call	$10	1	$10
Complete all study procedures	$200	1	$200
Total Study Compensation			$930

NIH required language when compensation is given:

If you are unable to finish the study, you will receive payment for the parts you completed.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Review Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

You will receive reimbursement for travel in this study.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.
- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.
- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH.

CONFLICT OF INTEREST (COI)

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

Quercis Pharma AG is providing Isoquercetin for this study to NIH without charge. No NIH employee involved in this study receives any payment or other benefits from Quercis Pharma AG.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor (NHLBI) or their agent(s)
- Qualified representatives from Querces AG, the pharmaceutical company who produces Isoquercetin.

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Arun Shet, M.D., at 301-827-6808 or: arun.shet@nih.gov. Or the research nurse, Ingrid Frey, RN at 301-402-6674. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.