

Natural Cycles

User Manual / Instructions for Use

Please read this manual before you start using Natural Cycles.

Indications for Use

Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).

Contraindications

There are no known contraindications for use of Natural Cycles.

Natural Cycles may not be right for you if

- You have a medical condition where pregnancy would be associated with a significant risk to the mother or the fetus. Using Natural Cycles does not guarantee 100% that you will not get pregnant. If pregnancy presents a significant risk, you should talk to your doctor about the best contraceptive option for you.
- You are currently taking hormonal birth control or undergoing hormonal treatment that inhibits ovulation. Natural Cycles will mainly provide red days if you do not ovulate. You can explore the app in Demo Mode until you discontinue your hormonal birth control or treatment.

Warnings

Natural Cycles

Navodila za uporabo / Navodila za uporabo

Preden začnete uporabljati Natural Cycles, preberite ta priročnik.

Indikacije za uporabo

Natural Cycles je samostojna programska aplikacija, namenjena ženskam, starim 18 let in več, spremljati njihovo plodnost. Natural Cycles se lahko uporablja za preprečevanje nosečnosti (kontracepcija) ali načrtovanje nosečnosti (spočetje).

Kontraindikacije

Ni znanih kontraindikacij za uporabo Natural Cycles.

Natural Cycles morda ne bo pravi za vas, če

- Imate zdravstveno stanje, pri katerem bi bila nosečnost povezana z velikim tveganjem za mater ali plod. Uporaba Natural Cycles ne jamči 100%, da ne boste zanosili. Če nosečnost predstavlja veliko tveganje, se posvetujte s svojim zdravnikom o najboljši možnosti kontracepcije za vas.
- Trenutno jemljete hormonsko kontracepcijo ali ste na hormonskem zdravljenju, ki zavira ovulacijo. Natural Cycles bo zagotovil rdeče dni, če ne boste ovulirali. Aplikacijo lahko raziskujete v demo načinu, dokler ne prekinete hormonske kontracepcije ali zdravljenja.

- ⚠ No method of contraception is 100% effective. Natural Cycles does not guarantee that you cannot get pregnant, it only informs you whether and when you can become pregnant based on the information that you enter into the application.
- ⚠ Even with using the app perfectly, you can still have an unintended pregnancy. Natural Cycles is 93% effective under typical use, which means that 7 women out of 100 get pregnant during 1 year of use. With using the app perfectly, i.e. if you never have unprotected intercourse on red days, Natural Cycles is 98% effective, which means that 2 women out of 100 get pregnant during 1 year of use.
- ⚠ On red days, you must either abstain or use protection, such as condoms or another form of barrier protection, to prevent pregnancy. If you have not been using a non-hormonal method of contraception before, make sure to have a method on hand to use during red days.
- ⚠ Our data show that women transitioning to Natural Cycles from hormonal contraception have a higher risk of becoming pregnant due to generally not yet being accustomed to using other forms of protection, such as a condom or another form of barrier protection.
- ⚠ If you are discontinuing hormonal contraception, you may first experience a withdrawal bleed, which is much lighter than your true period. You will normally get your true period a few weeks later. Withdrawal bleeding should not be entered as "period". If you are unsure if you are experiencing withdrawal bleeding or a period, please consult your doctor.
- ⚠ Natural Cycles does not protect against sexually transmitted infections (STIs). Use a condom to protect against STIs.
- ⚠ Always check your fertility status for the day. Be aware that fertility predictions for upcoming days are only predictions and may change in the future. If you are unsure of your fertility status and can't access the app, abstain or use protection in the meantime.
- ⚠ If you are exploring the demo version of the app, this is for informational or instructional purposes only and does not display real data. Do not use the information displayed in Demo Mode for contraceptive purposes.
- ⚠ If you have taken the emergency contraceptive pill, you should indicate it in the app. You can then continue measuring your temperature as normal and the algorithm will take the additional hormones from the pill into account. Note that the bleeding you may

Opozorila

- ⚠ Št kontracepcijsko metodo je 100% učinkovit. Natural Cycles ne jamči, da ne morete zanositi, samo vas obvesti, ali in kdaj lahko zanosite, na podlagi podatkov, ki jih vnesete v prijavo.
- ⚠ Tudi če popolnoma uporabljate aplikacijo, lahko še vedno pride do nenamerne nosečnosti. Natural Cycles je pri tipični uporabi 93% učinkovit, kar pomeni, da 7 žensk od 100 zanosi v enem letu uporabe. Če popolnoma uporabljate aplikacijo, tj. Če nikoli nimate nezaščitenega spolnega odnosa v rdečih dneh, je Natural Cycles 98% učinkovit, kar pomeni, da 2 ženski od 100 zanosita v enem letu uporabe.
- ⚠ Red V rdečih dneh se morate vzdržati ali uporabljati zaščito, na primer kondome ali drugo obliko zaščite, da preprečite nosečnost. Če doslej niste uporabljali nehormonske metode kontracepcije, imejte pri roki metodo za uporabo v rdečih dneh.
- ⚠ Data Naši podatki kažejo, da imajo ženske, ki prehajajo na Natural Cycles iz hormonske kontracepcije, večje tveganje za zanositev, ker se na splošno še niso navadile uporabljati drugih oblik zaščite, na primer kondoma ali druge oblike zaščite.
- ⚠ Če prekinete hormonsko kontracepcijo, lahko najprej doživite odtegnitveno krvavitev, ki je veliko lažja od vaše prave menstruacije. Pravo menstruacijo običajno dobite nekaj tednov kasneje. Odtegnitvene krvavitve ne smemo vnesti kot "obdobje". Če niste prepričani, ali imate odtegnitveno krvavitev ali menstruacijo, se posvetujte z zdravnikom.
- ⚠ Natural Cycles ne ščiti pred spolno prenosljivimi okužbami (SPO). Za zaščito pred spolno prenosljivimi okužbami uporabite kondom.
- ⚠ Vedno preverite stanje plodnosti za ta dan. Zavedajte se, da so napovedi plodnosti za prihodnje dni le napovedi in se lahko v prihodnosti spremenijo. Če niste prepričani o svojem stanju plodnosti in ne morete dostopati do aplikacije, se medtem vzdržite ali uporabite zaščito.

experience a few days after taking emergency contraception is not the same as your regular period and should not be entered into the app. If your period is more than one week late after it would normally start you should take a pregnancy test.

Precautions

- As a contraceptive, Natural Cycles may be less suitable for you if you have irregular menstrual cycles (i.e. cycles with length less than 21 days or greater than 35 days) and/or fluctuating temperatures as predicting fertility is more difficult in these circumstances. Natural Cycles' effectiveness as a contraceptive is not affected by irregular cycles, but you will experience an increased number of red days, which can reduce your satisfaction with Natural Cycles. This can be the case:
 - **If you discontinue hormonal contraception.** It can take several cycles after discontinuing hormonal contraception before becoming more regular again. You should expect more red days during these cycles and therefore expect to use protection or abstain more frequently.
 - **If you are breastfeeding.** For the first 4-6 months after giving birth, many women who are exclusively breastfeeding may not ovulate. Natural Cycles will detect your first ovulation 2 weeks before your first menstruation but until then you will only see red days in the app. Even though you are not ovulating, it is still important to use contraception or abstain from intercourse on red days.
 - **If you have medical conditions that lead to irregular cycles such as polycystic ovary syndrome (PCOS) or thyroid-related conditions.**
 - **If you experience symptoms of menopause.**
- When you start using Natural Cycles, it can take some time to get to know your unique cycle, resulting in an increased number of red days during your first 1-3 cycles. This is to ensure that the app is effective from the first day of use, and once Natural Cycles has detected your ovulation you are likely to receive more

△ Če raziskujete predstavitveno različico aplikacije, je to zgolj informativne ali poučne narave in ne prikazuje resničnih podatkov. Podatkov, prikazanih v demo načinu, ne uporabljajte za kontracepcijo.

△ Če ste vzeli tableto za nujno kontracepcijo, jo morate navesti v aplikaciji. Nato lahko nadaljujete z merjenjem temperature kot običajno in algoritem bo upošteval dodatne hormone iz tabletke. Upoštevajte, da krvavitev, ki jo lahko doživite nekaj dni po uporabi nujne kontracepcije, ni enaka vaši redni menstruaciji in je ne smete vnesti v aplikacijo. Če menstruacija po začetku menstruacije zamuja več kot en teden, morate opraviti test nosečnosti.

Previdnostni ukrepi

- Kot kontracepcijsko sredstvo je lahko Natural Cycles za vas manj primeren, če imate neredne menstrualne cikle (tj. Cikluse z dolžino manj kot 21 dni ali več kot 35 dni) in/ali nihanje temperatur, saj je napovedovanje plodnosti v teh okoliščinah težje. Nepravilni ciklusi ne vplivajo na učinkovitost Natural Cycles 'kot kontracepcije, vendar boste doživeli povečano število rdečih dni, kar lahko zmanjša vaše zadovoljstvo z Natural Cycles. Lahko je tako:
 - **Če ste prenehali s hormonsko kontracepcijo .** Po prekinitvi hormonske kontracepcije lahko traja več ciklov, preden postane spet bolj redna. V teh ciklih bi morali pričakovati več rdečih dni, zato pričakujte, da boste uporabljali zaščito ali se bolj vzdržali.
 - **Če dojite .** Prve 4-6 mesecev po porodu mnoge ženske, ki dojijo izključno, morda ne bodo ovulirale. Natural Cycles bo zaznala vašo prvo ovulacijo 2 tedna pred prvo menstruacijo, do takrat pa boste v aplikaciji videli le rdeče dni. Čeprav nimate ovulacije, je še vedno pomembno, da uporabite kontracepcijo ali se vzdržite spolnega odnosa v rdečih dneh.
 - **Če imate zdravstvene težave, ki vodijo v nepravilne cikle, kot je sindrom policističnih**

green days. It is important to note that you can rely on the fertility status indicated by the app from the first day of use.

- Always make sure to update your software app, so that you have the latest version. Natural Cycles recommends that you set your smartphone to update the app automatically.
- To ensure that your temperature measurements are accurate always use a basal thermometer to take your temperature.
- Always follow the directions for 'Measuring Your Temperature' stated below in order to increase the accuracy of ovulation detection.

Checklist

To get started with Natural Cycles you will need the following:

1. A Natural Cycles account

You can access Natural Cycles via your web browser, by visiting www.naturalcycles.com.

For access via the app, download the app on your Android, iPhone or iPad on Google Play or the App Store. Follow the registration steps to create your personal account. Make sure the device you use to access Natural Cycles is connected to the internet. Your Natural Cycles account is personal and should not be used by anyone except you.

2. A Basal thermometer

To get started you will need a basal thermometer. Basal thermometers are more sensitive than regular fever thermometers as they show two decimals (e.g. 36.72°C / 98.11°F). Temperature changes during the menstrual cycle are quite small, so to get the most out of Natural Cycles and receive more green days you will need the correct thermometer. The thermometer you use should be CE marked if you are in Europe or FDA cleared if you are in the US. A basal thermometer is included when you sign up for Natural Cycles with an annual subscription.

jajčnikov (PCOS) ali stanja, povezana s ščitnico .

- Če imate simptome menopavze.
- Ko začnete uporabljati Natural Cycles, lahko traja nekaj časa, da spoznate svoj edinstven cikel, kar povzroči povečano število rdečih dni v prvih 1-3 ciklih. S tem želimo zagotoviti, da bo aplikacija učinkovita od prvega dne uporabe, in ko bo Natural Cycles odkril ovulacijo, boste verjetno prejeli več zelenih dni. Pomembno je omeniti, da se lahko zanesete na stanje plodnosti, ki ga aplikacija navede od prvega dne uporabe.
- Vedno posodobite programsko opremo, tako da imate najnovejšo različico. Natural Cycles priporoča, da v pametnem telefonu nastavite samodejno posodabljanje aplikacije.
- Za zagotovitev natančnosti meritev temperature za merjenje temperature uporabite bazalni termometer.
- Vedno sledite spodnjim navodilom za „Merjenje vaše temperature“, da povečate natančnost zaznavanja ovulacije.

Kontrolni seznam

Za začetek uporabe Natural Cycles boste potrebovali naslednje:

1. Račun Natural Cycles

Do Natural Cycles lahko dostopate prek spletnega brskalnika, tako da obiščete www.naturalcycles.com . Za dostop prek aplikacije prenesite aplikacijo na svoj Android, iPhone ali iPad v Googlu Play ali App Store. Sledite korakom za registracijo, da ustvarite svoj osebni račun. Prepričajte se, da je naprava, s katero dostopate do Natural Cycles, povezana z internetom. Vaš račun Natural Cycles je osebni in ga ne sme uporabljati nihče razen vas.

2. Bazalni termometer

Za začetek boste potrebovali bazalni termometer. Bazalni termometri so občutljivejši od običajnih termometrov z vročino, saj prikazujejo dve decimalni mesti (npr. 36,72 ° C / 98,11 ° F). Temperaturne spremembe med menstrualnim

3. Ovulation tests (optional)

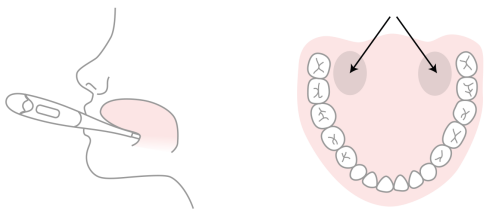
Ovulation (LH) tests are urine test strips which detect the surge of luteinizing hormone that occurs 1-2 days before ovulation. It is optional to use LH tests with Natural Cycles, but they can help to increase the accuracy of detecting ovulation and can, therefore, increase the number of green days you will see if you are preventing a pregnancy. Using LH tests will not affect the effectiveness of Natural Cycles as a contraceptive. If you are planning a pregnancy, we recommend using LH tests as they can help to find your most fertile days. You can purchase LH tests at shop.naturalcycles.com or from within the app itself.

Measuring your temperature

How to measure

Follow the user manual provided with your basal body temperature thermometer. If the thermometer was provided to you by Natural Cycles we recommend that you follow these steps when measuring your temperature:

1. Place the thermometer in your mouth and under your tongue, as far back as possible, next to the root of your tongue as depicted in the diagrams below.



2. Only press the power button once the thermometer is in your mouth and in place.
3. Try to keep still while measuring, close your mouth to keep any cool air out and breathe through your nose.

ciklusom so precej majhne, zato, da kar najbolje izkoristite Natural Cycles in prejmete več zelenih dni, boste potrebovali pravi termometer. Termometer, ki ga uporabljate, mora imeti oznako CE, če ste v Evropi, ali FDA, če ste v ZDA. Bazalni termometer je vključen, ko se prijavite za Natural Cycles z letno naročnino.

3. Preskusi ovulacije (neobvezno)

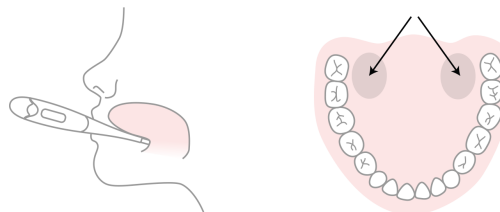
Ovulacijski (LH) testi so urinski testni trakovi, ki zaznajo porast luteinizirajočega hormona, ki se pojavi 1-2 dni pred ovulacijo. Uporaba testov LH z Natural Cycles ni obvezna, vendar lahko pomagajo povečati natančnost odkrivanja ovulacije in lahko zato povečajo število zelenih dni, ki jih boste videli, če preprečujete nosečnost. Uporaba testov LH ne bo vplivala na učinkovitost zdravila Natural Cycles kot kontracepcije. Če načrtujete nosečnost, priporočamo uporabo testov LH, ki vam lahko pomagajo najti vaše najbolj plodne dni. LH teste lahko kupite na shop.naturalcycles.com ali v sami aplikaciji.

Merjenje vaše temperature

Kako meriti

Sledite navodilom za uporabo, ki ste jih dobili s termometrom za bazalno telesno temperaturo. Če vam je termometer dal Natural Cycles, vam priporočamo, da pri merjenju temperature sledite tem korakom:

1. Termometer postavite v usta in pod jezik, kolikor je mogoče nazaj, poleg korena jezika, kot je prikazano na spodnjih diagramih.



2. Gumb za vklop pritisnite le, ko je termometer v ustih in na svojem mestu.

4. Wait until it beeps (approx. 30 seconds).
5. Once you have your reading, add the temperature into the app.

You can use the 'Measuring Training' and the 'Measuring Guide' in the app to check your measuring skills.

The thermometer will save your reading, so you can check your reading once again later. To do this press the "on" button once; the saved reading will appear for a few seconds before the temperature resets.

When to measure

Measure your temperature once a day, on as many days as possible, so that the algorithm can quickly get to know your unique cycle. Aim to measure at least 5 days a week. A tip to help you remember is to place your thermometer on top of your phone before going to bed.

Measure first thing in the morning when you wake up, before you get up and out of bed. Ideally measure at around the same time every day (within +/- 2 hours).

When to exclude temperatures

Certain circumstances may affect your basal temperature. This can lead to varying temperatures and make it harder for the algorithm to track your cycle. To help our algorithm learn about your cycle and accurately find ovulation, use the "Exclude temperature" function in the app if you:

- Feel hungover
- Slept differently (>2 hours more/less than usual)
- Feel sick

Remember that everyone is different with different routines and, for instance, little sleep might affect you more or less than others. Exclude your temperature only if you feel that something was out of the ordinary for you and you feel differently this morning because of it.

Medication can also affect your temperature. If you take regular medication it's worth consulting with your doctor to discover its impact on your basal body temperature.

3. Med merjenjem poskušajte ostati pri miru, zaprite usta, da ne pride ven hladnega zraka, in dihajte skozi nos.
4. Počakajte, da zasliši (pribl. 30 sekund).
5. Ko preberete, dodajte temperaturo v aplikacijo.

Če želite preveriti svoje merilne sposobnosti, lahko uporabite aplikacijo "Merilni trening" in "Merilni vodnik".

Termometer bo shranil vaše odčitke, zato jih lahko pozneje znova preverite. Če želite to narediti, enkrat pritisnite gumb za vklop; shranjeni odčitki se bodo prikazali nekaj sekund, preden se temperatura ponastavi.

Kdaj meriti

Izmerite svojo temperaturo enkrat na dan, v čim več dneh, da lahko algoritem hitro spozna vaš edinstven cikel. Meriti morate vsaj 5 dni na teden. Namig, ki si ga boste lažje zapomnili, je, da pred spanjem postavite termometer na telefon.

Najprej izmerite zjutraj, ko se zbudite, preden vstanete in vstanete iz postelje. V idealnem primeru merite vsak dan ob približno istem času (v +/- 2 urah).

Kdaj izključiti temperature

Nekatere okoliščine lahko vplivajo na vašo bazalno temperaturo. To lahko privede do spreminjanja temperatur in oteži algoritmu sledenje vašemu ciklu. Če želite našemu algoritmu pomagati spoznati vaš cikel in natančno najti ovulacijo, uporabite funkcijo »Izključi temperaturo« v aplikaciji, če:

- Občutite mačka
- Spali drugače (> 2 uri več/manj kot običajno)
- Počutite se slabo

Ne pozabite, da so vsi različni z različnimi rutinami in na primer malo spanja lahko vpliva na vas bolj ali manj kot na druge. Izključite svojo temperaturo le, če menite, da vam

Changing your thermometer

If you need to replace your thermometer, do this at the start of your period. A basal thermometer is highly accurate, but from one thermometer to another, there can be a small difference in how each one measures. For example, if one thermometer is showing one temperature, the second can show a 0.1°C difference. As the app is looking for the smallest differences in temperatures to be able to locate where you are in your cycle, you should only use one thermometer at a time. Do not change these during the course of a cycle, instead wait until a new cycle has started before changing your thermometer.

Natural Cycles products

Natural Cycles offers three modes for our users to choose from depending on their fertility goal:

- NC° Birth Control - for preventing pregnancy
- NC° Plan Pregnancy - for increasing chances of conception
- NC° Follow Pregnancy - for monitoring the course of a pregnancy

These three modes can be chosen by the user prior to signing up and then within the app, if the user would like to switch between modes.

Contraception: NC° Birth Control

How it works

Your daily morning routine with Natural Cycles is as follows:

1. Measure your temperature when you wake up as described in the section above.
2. Add your temperature and whether you have your period into the app. The view to add data will automatically open, or you can press the '+' icon in the top right-hand corner. You can also add additional data,

nekaj ni bilo v redu in se zaradi tega danes zjutraj počutite drugače.

Zdravila lahko vplivajo tudi na vašo temperaturo. Če jemljete redna zdravila, se je vredno posvetovati z zdravnikom, da ugotovite njihov vpliv na bazalno telesno temperaturo.

Menjava termometra

Če morate zamenjati termometer, to storite na začetku menstruacije. Bazalni termometer je zelo natančen, toda od enega termometra do drugega je lahko majhna razlika v tem, kako vsak meri. Na primer, če en termometer prikazuje eno temperaturo, lahko drugi pokaže 0,1 ° C razlike. Ker aplikacija išče najmanjše temperaturne razlike, da bi lahko ugotovila, kje ste v svojem ciklu, morate uporabiti samo en termometer naenkrat. Ne spreminjajte jih med ciklusom, raje počakajte do novega cikla se je začel, preden ste zamenjali termometer.

Natural Cycles izdelkov

Natural Cycles našim uporabnikom ponuja tri načine izbiranja glede na njihov cilj glede plodnosti:

- NC° Birth Control - za preprečevanje nosečnosti
- NC° Plan Pregnancy - za povečanje možnosti spočetja
- NC° Follow Pregnancy - za spremljanje poteka nosečnosti

Te tri načine lahko uporabnik izbere pred registracijo in nato v aplikaciji, če želi uporabnik preklopiti med načini.

Kontracepcija: NC° Birth Control

Kako deluje

Vaša dnevna jutranja rutina z Natural Cycles je naslednja:

1. Ko se zbudite, izmerite svojo temperaturo, kot je opisano v zgornjem razdelku.
2. V aplikacijo dodajte svojo temperaturo in ali imate menstruacijo. Pogled za dodajanje podatkov se bo

such as the result of ovulation (LH) test. Once you save today's data, the app will calculate your status for the day.

3. Check your fertility status for the day - every day. The app will provide your fertility status directly after your first set of data is entered. Your status for the day is displayed in red and green colors throughout the app.

Green = Not fertile



Green days indicate you are not fertile and can have sex without protection. Green days are indicated by a green outlined circle with the words "Not fertile" inside.

Red = Use protection



Red days indicate you are likely to be fertile and at risk of becoming pregnant. Use protection (such as condoms or another form of barrier protection) or abstain in order to prevent a pregnancy. Red days are indicated by a red outlined circle with the words "Use protection" inside.

The app will indicate your ovulation as well as when you have entered and are expected to have your period. The application also shows predictions for upcoming days and months. The predictions may change and should not be used as the final result, which is why you should check your status for the day - every day.

Summary of clinical studies - how effective is Natural Cycles for contraception?

Natural Cycles is 93% effective under typical use. Under perfect use, i.e. if you never have unprotected intercourse on red days, Natural Cycles is 98% effective.

Clinical studies have been conducted in order to evaluate the effectiveness of Natural Cycles for contraception. The current version of the algorithm (v.3) has been investigated on 15,570 women (on average 29 years old). At the end of the study, the following commonly used failure rates were determined:

samodejno odprl ali pa pritisnete ikono '+' v zgornjem desnem kotu. Dodate lahko tudi dodatne podatke, na primer rezultat testa ovulacije (LH). Ko shranite današnje podatke, bo aplikacija izračunala vaše stanje za dan.

3. Vsak dan preverite stanje plodnosti. Aplikacija bo zagotovila vaš status plodnosti takoj po vnosu prvega nabora podatkov. Vaše stanje za dan je prikazano v rdeči in zeleni barvi v celotni aplikaciji.

Zelena = Ni plodna



Zeleni dnevi kažejo, da niste plodni in da lahko spolno spolite brez zaščite. Zeleni dnevi so označeni z zelenim obrisanim krogom z besedami »Ni plodno«.

Rdeča = Uporabite zaščito



Rdeči dnevi kažejo, da ste verjetno plodni in obstaja nevarnost zanositve. Uporabite zaščito (na primer kondome ali drugo obliko pregradne zaščite) ali se vzdržite, da preprečite nosečnost. Rdeči dnevi so označeni z rdečim obrisanim krogom z napisom »Uporabi zaščito«.

Aplikacija bo prikazala vašo ovulacijo, pa tudi, kdaj ste vstopili in naj bi imeli menstruacijo. Aplikacija prikazuje tudi napovedi za prihodnje dni in mesece. Napovedi se lahko spremenijo in jih ne bi smeli uporabljati kot končni rezultat, zato morate vsak dan preverjati svoje stanje - vsak dan.

Povzetek kliničnih študij - kako učinkovit je Natural Cycles za kontracepcijo?

Natural Cycles je pri tipični uporabi 93% učinkovit. Pri popolni uporabi, tj. Če nikoli nimate nezaščitenega spolnega odnosa v rdečih dneh, je Natural Cycles 98% učinkovit.

Klinične študije so bile izvedene za oceno učinkovitosti Natural Cycles za kontracepcijo. Trenutna različica algoritma (v.3) je bila raziskana pri 15.570 ženskah (v povprečju starih

1. The app has a method failure rate of 0.6, which is a measurement of how often the app incorrectly displays a green day when the woman is actually fertile and gets pregnant after having unprotected intercourse on this green day. This means that 0.6 out of 100 women who use the app for one year get pregnant due to this type of failure.
2. The app has a perfect use Pearl Index of 1, which means that 1 out of 100 women who use the app for one year and who get pregnant will do so either because:
 - a. They had unprotected intercourse on a green day that was falsely attributed as non-fertile (i.e., method failure); or
 - b. They had protected intercourse on a red day, but the chosen method of contraception failed.
3. The app has a typical use Pearl Index of 6.5, which means that in total 6.5 women out of 100 get pregnant during one year of use due to all possible reasons (e.g. falsely attributed green days, having unprotected intercourse on red days, and failure of the contraceptive method used on red days).

Summary of clinical data from 15,570 women on the effectiveness of Natural Cycles of the current algorithm version.

Algorithm Version	v.3
Study Date Range	Sept 2017 - Apr 2018
# women	15,570
Exposure time (Women-years)	7,353

29 let). Na koncu študije so bile ugotovljene naslednje pogosto uporabljene stopnje napak:

1. Aplikacija ima stopnjo neuspeha metode 0,6, kar je merilo, kako pogosto aplikacija nepravilno prikaže zeleni dan, ko je ženska dejansko plodna in zanosi, potem ko je imela na ta zeleni dan nezaščiten spolni odnos. To pomeni, da 0,6 od 100 žensk, ki eno leto uporabljajo aplikacijo, zaradi takšne napake zanosijo.
2. Aplikacija odlično uporablja indeks Pearl 1, kar pomeni, da bo 1 od 100 žensk, ki uporabljajo aplikacijo eno leto in zanosile, to storilo bodisi zaradi:
 1. Imeli so nezaščiten spolni odnos na zeleni dan, ki je bil napačno pripisan neplodnosti (tj. Napaka metode); ali
 2. Na rdeč dan sta imela zaščiteni spolni odnos, vendar izbrana metoda kontracepcije ni uspela.
3. Aplikacija ima tipično uporabo Pearl Index 6,5, kar pomeni, da skupaj 6,5 od 100 žensk zanosi v enem letu uporabe zaradi vseh možnih razlogov (npr. Napačno pripisani zeleni dnevi, nezaščiten spolni odnos v rdečih dneh in neuspeh metoda kontracepcije, ki se uporablja v rdečih dneh).

Povzetek kliničnih podatkov 15.570 žensk o učinkovitosti Natural Cycles trenutne različice algoritma.

Algoritem Različica	v.3
Časovno obdobje študija	September 2017 - Aprila 2018
# žensk	15.57
Čas izpostavljenosti (ženska leta)	7,353

# pregnancies [worst-case]	475 [584]
Typical use PI (95% confidence interval) [worst-case]	6.5 (5.9-7.1) [7.9]
Method failure rate (95% confidence interval)	0.6 (0.4-0.8)

Effectiveness of Natural Cycles for two subgroups - women who used hormonal contraception within 60 days prior to using the app and women who did not use hormonal contraception within 12 months prior to using the app.

Subgroup	Typical Use PI (95% confidence interval)
Recent Hormonal Contraception 3779 women	8.6 % (7.2-10.0)
No Hormonal Contraception 8412 women	5.0 % (4.3-5.7)

You can find an overview of the effectiveness of different contraceptive methods in the Appendix of this manual. This will help you to understand the expected effectiveness of all forms of contraception.

Instructions if you are discontinuing hormonal contraception

Type of Contraception	When can you start Natural Cycles?
The Pill (Combined, Medium or Mini)	We recommend that you finish all the active pills of your packet. You can start using Natural Cycles as soon as you finish. You will have a high

# nosečnosti [v najslabšem primeru]	475 [584]
Tipična uporaba PI (95% interval zaupanja) [v najslabšem primeru]	6.5 (5,9-7,1) [7.9]
Stopnja neuspeha metode (95% interval zaupanja)	0,6 (0,4-0,8)

Učinkovitost zdravila Natural Cycles za dve podskupini - ženske, ki so v 60 dneh pred uporabo aplikacije uporabljale hormonsko kontracepcijo, in ženske, ki v 12 mesecih pred uporabo aplikacije niso uporabljale hormonske kontracepcije.

Podskupina	PI tipične uporabe (95% interv
Nedavna hormonska kontracepcija 3779 žensk	8,6 % (7,2-10,0)
Brez hormonske kontracepcije 8412 žensk	5,0 % (4,3-5,7)

Pregled učinkovitosti različnih kontracepcijskih metod najdete v Dodatku tega priročnika. To vam bo pomagalo razumeti pričakovano učinkovitost vseh oblik kontracepcije.

Navodila, če prenehate s hormonsko kontracepcijo

Vrsta kontracepcije	Kdaj lahko začnete Natural Cycles?
Tablete (kombinirane, srednje ali mini)	Priporočamo, da dokončate vse aktivne tablete svojega paketa. Natural Cycles lahko začnete uporabljati takoj, ko končate. Za začetek boste imeli veliko rdečih dni, vendar se bo to sčasoma izboljšalo.

	number of red days to begin with but this will improve over time.	Hormonska IUD (intrauterina naprava)	Z uporabo Natural Cycles lahko začnete dan po odstranitvi.
Hormonal IUD (Intrauterine Device)	You can start using Natural Cycles the day after it has been removed.	Kontracepcijski vsadek	Z uporabo Natural Cycles lahko začnete dan po odstranitvi.
Contraceptive Implant	You can start using Natural Cycles the day after it has been removed.	Hormonski obliž, hormonski kontracepcijski obroč	Z uporabo Natural Cycles lahko začnete dan po odstranitvi. Za začetek boste imeli veliko rdečih dni, vendar se bo to sčasoma izboljšalo.
Hormonal Patch, Hormonal Contraceptive Ring	You can start using Natural Cycles the day after it has been removed. You will have a high number of red days to begin with this but this will improve over time.	Kontracepcijske injekcije	Z uporabo Natural Cycles lahko začnete, ko učinek injekcije izgine. To traja 8-13 tednov, odvisno od tega, katero injekcijo ste imeli.
Contraceptive Injection	You can start using Natural Cycles when the effect of the injection has worn off. This takes 8-13 weeks depending on which injection you had.		

If you are discontinuing hormonal contraception you may first experience a withdrawal bleed, which is much lighter than your true period. You will normally get your true period a few weeks later. Withdrawal bleeding should **not** be entered in the app as "period".

Note: a copper IUD does not contain hormones and does therefore not inhibit ovulation. You can thus use Natural Cycles alongside a copper IUD to get insights on your body and menstrual cycle without having to use a barrier method on red days.

If you become pregnant on Natural Cycles

If your period is overdue and your temperature does not drop, you may be pregnant and the app will encourage you to take a pregnancy test to confirm the pregnancy. If the test is positive, please talk to your doctor and indicate it in the app.

Če prekinete hormonsko kontracepcijo, lahko najprej doživite odtegnitveno krvavitev, ki je veliko lažja od vaše prave menstruacije. Pravo menstruacijo običajno dobite nekaj tednov kasneje. Odtegnitvene krvavitve **ne** smete vnesti v aplikacijo kot »obdobje«.

Opomba: bakrena IUD ne vsebuje hormonov in zato ne zavira ovulacije. Tako lahko uporabite Natural Cycles skupaj z bakrenim IUD -om, da dobite vpogled v svoje telo in menstrualni cikel, ne da bi morali v rdečih dneh uporabljati pregradno metodo.

Če zanosite Natural Cycles









Če menstruacija zamuja in temperatura ne pade, ste morda noseči in aplikacija vas bo spodbudila, da opravite test nosečnosti, da potrdite nosečnost. Če je test pozitiven, se pogovorite s svojim zdravnikom in ga navedite v aplikaciji.

NC° Plan Pregnancy

Ko načrtujete nosečnost, med prijavo v aplikaciji izberite NC° Plan Pregnancy. Če ste že prijavljeni v aplikacijo, pojdite na stran z nastavitvami in izberite NC° Plan Pregnancy. V tem načinu je vaša plodnost prikazana kot lestvica, tako da lahko









NC° Plan Pregnancy

When you are planning a pregnancy, select NC° Plan Pregnancy while signing up in the app. If you are already signed into the app, you can go to the settings page and choose NC° Plan Pregnancy. In this mode, your fertility is displayed as a scale, so you can identify the days you are most likely to become pregnant. The same morning routine as in NC° Birth Control mode applies here as well - measure, add data and check your fertility status.

-  Peak fertility
-  Very high fertility
-  High fertility
-  Medium fertility
-  Low fertility
-  Fertility unlikely
-  More data needed
-  Not fertile

When you're planning a pregnancy, we recommend taking LH tests since the occurrence of LH coincides with your most fertile days. If your period is overdue and your temperature does not drop, the app will encourage you to take a pregnancy test to confirm the pregnancy.

določite dneve, ko boste najverjetneje zanosili. Enaka jutranja rutina kot v načinu NC° Birth Control velja tudi tukaj - izmerite, dodajte podatke in preverite stanje plodnosti.

-  Najvišja rodnost
-  Zelo visoka rodnost
-  Visoka rodnost
-  Srednja rodnost
-  Nizka rodnost
-  Plodnost malo verjetna
-  Potrebni je več podatkov
-  Ni plodno

Ko načrtujete nosečnost, priporočamo, da opravite teste LH, saj pojav LH sovpada z vašimi najbolj plodnimi dnevi. Če menstruacija zamuja in temperatura ne pade, vas bo aplikacija spodbudila, da opravite test nosečnosti, da potrdite nosečnost.

NC° Follow Pregnancy

Ko ste noseči, lahko aplikacijo uporabite kot koledar nosečnosti in spremljate svoj tedenski razvoj in razvoj vašega otroka.

Demo način

NC° Follow Pregnancy

Once you are pregnant, the app can be used as a pregnancy calendar and you can follow your weekly development and the development of your baby.

Demo Mode

In Demo Mode you can take a tour of the app. This is for demonstration purposes only, demo mode cannot provide you with any fertility information.

If you are currently on hormonal contraception you will access the app in Demo Mode. Once you stop using hormonal contraception you can then easily access the full version of the app. The app will now function for contraception or for planning a pregnancy.

Problems/ Troubleshooting

If you cannot access the application, the application is malfunctioning, or if you suspect something is wrong with your current fertility status, please follow the steps below:

1. Use protection, such as a condom or another form of barrier protection, until the error has been fixed.
2. Please contact our service desk via help.naturalcycles.com and our trained support agents will assist you.
3. Serious incidents involving this device should be reported both to Natural Cycles and to the competent authority in your country. A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:
 - a. the death of a patient, user or other person,
 - b. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
 - c. a serious public health threat;

V predstavitvenem načinu si lahko ogledate aplikacijo. To je samo za predstavitvene namene, demo način vam ne more dati nobenih podatkov o plodnosti.

Če trenutno uporabljate hormonsko kontracepcijo, boste do aplikacije dostopali v demo načinu. Ko nehatte uporabljati hormonsko kontracepcijo, lahko preprosto dostopate do celotne različice aplikacije. Aplikacija bo zdaj delovala za kontracepcijo ali za načrtovanje nosečnosti.

Težave/ odpravljanje težav

Če ne morete dostopati do aplikacije, aplikacija ne deluje pravilno ali če sumite, da je kaj narobe s trenutnim stanjem plodnosti, sledite spodnjim korakom:

1. Uporabljajte zaščito, na primer kondom ali drugo obliko pregradne zaščite, dokler napake ne odpravite.
2. Obrnite se na našo servisno službo prek help.naturalcycles.com in naši usposobljeni zastopniki vam bodo pomagali.
3. O resnih incidentih s to napravo je treba poročati Natural Cycles in pristojnemu organu v vaši državi. "Resni incident" pomeni vsak incident, ki je neposredno ali posredno vodil, bi lahko povzročil ali bi lahko privedel do katerega koli od naslednjega:
 1. smrt bolnika, uporabnika ali druge osebe,
 2. začasno ali trajno resno poslabšanje zdravstvenega stanja pacienta, uporabnika ali druge osebe,
 3. resna grožnja javnemu zdravju;

Pregled aplikacije

Vaše stanje plodnosti za ta dan je prikazano skozi različne poglede v aplikaciji.

Application Overview

Your fertility status for the day is shown through different views within the app.

Calendar tab

This tab provides the overview of today's fertility and gives insights into the data logged in the past through various views as described below.

Today view

On this screen, you will get all of the info you need in one glance. A screen to enter your temperature pops up automatically when you open your app in the morning. Once you've entered your data, your fertility status will appear as a colored circle with additional information inside. Below the circle, you will see the weekly predictions. You can add or update your input data, such as temperature, period, or LH tests, at any time by tapping the '+' icon.

Month view

Tap the "Month" tab in the calendar view to access the monthly view. Here you can see your predicted red and green days for the month, as well as when you are predicted to ovulate and have your period. These may change over time, so you should only rely on the information provided in the "Today" view for contraceptive or pregnancy planning purposes. You can easily access your past data by tapping on any past day.

History view

The "History" tab is a log of all the data that you've previously entered. Scroll up and down to view your temperature readings, all added data for each cycle day, as well as an extraction of your notes.

Zavihek Koledar

Na tem zavihku je pregled današnje plodnosti in vpogled v podatke, ki so bili v preteklosti zabeleženi skozi različne poglede, kot je opisano spodaj.

Današnji pogled

Na tem zaslonu boste naenkrat dobili vse potrebne informacije. Ko zjutraj odprete aplikacijo, se samodejno prikaže zaslon za vnos temperature. Ko vnesete svoje podatke, bo vaš status plodnosti prikazan kot barvni krog z dodatnimi informacijami. Pod krogom boste videli tedenske napovedi. Vhodne podatke, kot so testi temperature, obdobja ali LH, lahko kadar koli dodate ali posodobite tako, da se dotaknete ikone »+«.

Mesečni pogled

Dotaknite se zavihka »Mesec« v pogledu koledarja za dostop do mesečnega pogleda. Tukaj si lahko ogledate predvidene rdeče in zelene dni za mesec, pa tudi, kdaj naj bi ovulirali in imeli menstruacijo. Ti se lahko sčasoma spremenijo, zato se za namene kontracepcije ali načrtovanja nosečnosti zanašajte le na informacije, navedene v pogledu »Danes«. Do preteklih podatkov lahko preprosto dostopate tako, da tapnete kateri koli pretekli dan.

Pogled zgodovine

Zavihek »Zgodovina« je dnevnik vseh podatkov, ki ste jih prej vnesli. Pomaknite se navzgor in navzdol, da si ogledate odčitke temperature, vse dodane podatke za vsak dan cikla in izvleček zapiskov.

Pogled grafa

Graf je vizualizacija vaše temperaturne krivulje, ki se bo še naprej razvijala med merjenjem skozi celoten cikel. Vidni so tudi podatki o ovulaciji, menstruaciji in plodnih dneh. Povlecite od leve proti desni, da si ogledate pretekle cikle, in se dotaknite »3 cikli« ali »6 ciklov«, da jih primerjate med seboj. Dostopate lahko tudi do načina za primerjavo, da primerjate svoje obdobje in dolžino cikla, nihanje temperature in okno ovulacije ter dan.

Zavihek Moj cikel

Graph view

The graph is a visualization of your temperature curve which will continue to develop as you measure throughout your cycle. Information about ovulation, period, and fertile days is also visible. Swipe from left to right to view your past cycles, and tap '3 cycles' or '6 cycles' to compare them to each other. You can also access the compare mode to compare your period and cycle length, temperature variation and ovulation window and day.

My Cycle tab

This view will give you an overview of your cycle data. You will see your cycle length and regularity, as well as a detailed analysis of the phases of your menstrual cycle - follicular and luteal phase.

Messages tab

These are gentle messages and useful information we send you, so you can get the very most out of your Natural Cycles experience. Messages are tailored to your unique cycle and are only sent if they are relevant to you. Learn more about your body, enjoy knowing about when your period is coming up, and more.

The messages can also contain instructions for better use of the app such as:

- If you enter a temperature that is unreasonably high or low, a message will inform you immediately to verify the entered temperature.
- If you enter that you had unprotected sex on a red day in the Natural Cycles application, it displays a cautionary message.
- An in-app message will be sent to you if your period is overdue and your temperature does not drop, as this indicates that you may be pregnant. The message will encourage you to take a pregnancy test.
- On some days, an in-app message will ask you to take an LH test. LH tests are optional to use but can

Ta pogled vam bo dal pregled vaših podatkov o ciklu. Videli boste dolžino in pravilnost svojega cikla ter podrobno analizo faz vašega menstrualnega cikla - folikularne in lutealne faze.

Zavihek Sporočila

To so nežna sporočila in koristne informacije, ki vam jih pošiljamo, zato lahko iz svojih Natural Cycles izkušeni kar najbolje izkoristite. Sporočila so prilagojena vašemu edinstvenemu ciklu in so poslana le, če so za vas pomembna. Izvedite več o svojem telesu, uživajte v tem, kdaj prihaja menstruacija, in še več.

Sporočila lahko vsebujejo tudi navodila za boljšo uporabo aplikacije, na primer:

- Če vnesete neprimerno visoko ali nizko temperaturo, vas bo takoj obvestilo, da preverite vneseno temperaturo.
- Če v aplikacijo Natural Cycles vnesete, da ste imeli rdeč dan nezaščiten spolni odnos, se prikaže opozorilo.
- Če menstruacija zamuja in temperatura ne pade, vam bomo poslali sporočilo v aplikaciji, saj to pomeni, da ste morda noseči. Sporočilo vas bo spodbudilo k preizkusu nosečnosti.
- V nekaterih dneh vas bo sporočilo v aplikaciji pozvalo, da opravite test LH. LH testi so neobvezni za uporabo, vendar lahko pomagajo povečati število zelenih dni na cikel.

Zavihek Moji podatki

Na tem zavihku boste našli uporaben vpogled v meritve in podatke, ki jih vnesete v aplikacijo. Vodil vas bo skozi pot oblikovanja navade in vas ob tem obvestil o vašem napredku.

Zavihek Nauči se

To je vstopna točka za vse izobraževalne vsebine, ki jih ponuja aplikacija. Tu lahko izveste o menstrualnem ciklu,

help to increase the number of green days per cycle.

My Data tab

This tab will provide you with useful insights on your measuring and on the data that you put into the app. It will guide you through the journey of building a habit and will notify you along the way on your progress.

Learn tab

This is an entry point to all the educational content the app provides. Here you can learn about the menstrual cycle, how to notice patterns in your body and how well the algorithm knows you based on the data you provide.

Top menu

Under the top menu, you can access and manage all the information regarding your personal profile, the app and privacy settings, and your account including subscriptions. Here you can also manage whether or not you will get reminders about when to use protection, take an LH test, expect PMS, measure your temperature and check your breasts. Note that you must enable Natural Cycles to send you push notifications in your device settings to receive these.

Offline mode

When you are offline you can continue to add your temperature and other data to the app. When offline, the app does not calculate your fertility status. Instead, the app will show an orange outlined circle indicating your status as "Use protection". Use protection (such as condoms or another form of barrier protection) or abstain until you are back online and the app has calculated today's fertility status.

Platform description

Natural Cycles Application Version: 4.2.0 and onwards

kako opazite vzorce v svojem telesu in kako dobro vas algoritem pozna na podlagi podatkov, ki jih posredujete.

Zgornji meni

V zgornjem meniju lahko dostopate in upravljate vse podatke o svojem osebni profilu, aplikaciji in nastavitvah zasebnosti ter računu, vključno z naročninami. Tu lahko tudi določite, ali boste dobili opomnike o tem, kdaj uporabiti zaščito, opravite test LH, pričakujete PMS, izmerite temperaturo in preverite dojke. Upoštevajte, da morate omogočiti Natural Cycles za pošiljanje potisnih obvestil v nastavitvah naprave, da jih prejmete.

Način brez povezave

Ko ste brez povezave, lahko aplikaciji še naprej dodajate svojo temperaturo in druge podatke. Ko je brez povezave, aplikacija ne izračuna vašega stanja plodnosti. Namesto tega bo aplikacija prikazala oranžno obrisan krog, ki označuje vaš status »Uporabi zaščito«. Uporabljajte zaščito (na primer kondome ali drugo obliko pregradne zaščite) ali se vzdržite, dokler niste spet na spletu in aplikacija ne izračuna današnjega stanja plodnosti.

Opis platforme

Natural Cycles Različica aplikacije: 4.2.0 in naprej

Različica medicinskega pripomočka: C

Naprave, ki jih lahko uporabite za dostop do aplikacije:

- Mobilni telefon z operacijskim sistemom Android (različica 7 ali novejša) ali iOS (različica 12 ali novejša), 250 kb / s ali hitrejši internet.
- Računalnik ali tablični računalnik z internetnim brskalnikom: Google Chrome, Apple Safari. 250 kb / s ali hitrejši internet.

Dostop do navodil za uporabo

Navodila za uporabo najdete na spletu na spletnem mestu Natural Cycles in v svoji aplikaciji na strani »Regulativno«.

Medical Device version: C

Devices that may be used to access the application:

- A mobile phone running Android OS (version 7 or above) or iOS (version 12 or above), 250 kbps or faster internet.
- A computer or tablet with an Internet browser: Google Chrome, Apple Safari. 250 kbps or faster internet.

Accessing the Instructions for Use

The Instructions for Use can be found online on the Natural Cycles website and in your app under the “Regulatory” page.

If you would like a paper copy of the Instructions for Use we will send you one at no cost. Contact customer support with your request.

Če želite papirni izvod navodil za uporabo, vam ga bomo poslali brezplačno. S svojo zahtevo se obrnite na podporo strankam.

Prenehajte uporabljati Natural Cycles

Ko se prijavite za Natural Cycles, ne glede na to, ali gre za mesečno ali letno naročnino, jo boste morali preklicati, če ne želite, da se naročnina samodejno podaljša za naslednje obdobje podaljšanja. Odpoved naročnine je treba opraviti najmanj 24 ur pred predvidenim podaljšanjem naročnine. Za popoln opis, kako uspešno preklicati naročnino, obiščite help.naturalcycles.com. Za več informacij o tem, kako Natural Cycles obdeluje vaše podatke, glejte naš pravilnik o zasebnosti.

Varnost

Natural Cycles ohraniti visoko raven varnosti in zasebnosti podatkov v naši aplikaciji. Aplikacijo spremljajo varnostni dogodki in kršitve podatkov. Če bi prišlo do varnostnega dogodka ali kršitve podatkov, bo težava v skladu z našimi uveljavljenimi postopki nujno odpravljena in rešena, vi kot uporabnik pa boste prejeli informacije, ki jih potrebujete glede vaše nadaljnje varne in zaščitene uporabe aplikacije.

Močno priporočamo, da za zaščito računa pred nepooblaščenno uporabo izberete močno geslo. Čeprav to ni priporočljivo, če se odločite, da boste prijavo delili z nekom, to storite na lastno odgovornost. Upoštevajte, da lahko dostop vedno prekličete tako, da spremenite geslo za svoj račun in se obrnete na podporo, da zaprete obstoječe seje.

Pazite na e-poštna sporočila ali sporočila, ki vas prosijo, da vnesete svoje Natural Cycles podatke za prijavo. Natural Cycles vam običajno ne bo pošiljal e-poštnih sporočil z vprašanjem vašega gesla, razen če ste sami začeli ta postopek prek podpore ali ponastavitve gesla.

Cease using Natural Cycles

When you sign up for Natural Cycles, whether it's for a Monthly or Yearly subscription, you will need to cancel it if you don't want your subscription to be automatically renewed for the next renewal period. Cancellation of your subscription must be done at least 24 hours before the subscription is scheduled to be renewed. Please refer to help.naturalcycles.com for a full description on how to cancel your subscription successfully. Please refer to our Privacy policy for further information on how Natural Cycles processes your data.

Security

Natural Cycles maintain a high security and data privacy level in our application. The application is monitored for security events and data breaches. If a security event or data breach should occur, the issue will be contained and resolved with urgency according to our established processes and you as a user will receive the information you need regarding your continued safe and secure use of the application.

It is strongly recommended that you choose a strong password to protect your account from unauthorized use. While not recommended, if you should choose to share your login with somebody, you do so at your own risk. Keep in mind that you can always revoke access by changing the password to your account and contacting support in order to close existing sessions.

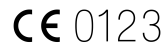
Watch out for emails or messages asking you to provide your Natural Cycles login details. Natural cycles will not usually send you emails asking for your password, unless you have initiated this process yourself via support or a password reset.

Splošne informacije

Pojasnilo simbolov



Proizvajalec



CE oznaka



Pozor



Navodila za uporabo/Navodila za uporabo

Izjava ES o skladnosti

Ime proizvajalca:

NaturalCycles Nordic AB

Naslov proizvajalca:

St Eriksgatan 63b
112 34 Stockholm
Švedska

Pomoč strankam:

help.naturalcycles.com

Ime naprave:

Natural Cycles

Izjavljamo, da ta izdelek izpolnjuje vse veljavne zahteve Uredbe (EU) 2017/745 za medicinske pripomočke (MDR) in nosi oznako CE0123.

Datum objave:

December 2021

Različica dokumenta:

SI v2.15

General information

Explanation of symbols



Manufacturer

CE 0123 CE Mark



Caution



User Manual/Instructions for Use

EC Declaration of Conformity

Name of the Manufacturer:

NaturalCycles Nordic AB

Address of the Manufacturer:

St Eriksgatan 63b
112 34 Stockholm
Sweden

Customer support:

help.naturalcycles.com

Device Name:

Natural Cycles

We declare that this product meets all applicable requirements of the Regulation (EU) 2017/745 for medical devices (MDR) and bears the mark CE0123.

Date of publication:

November 2021

Document version:

EU & US v2.15

Onboarding information/Informacije o vkrcanju

angleščina	Slovenščina
<p>How would you like to use Natural Cycles?</p> <ul style="list-style-type: none"> • Prevent pregnancy • Plan a pregnancy • Follow your pregnancy 	<p>Kako želite uporabiti Natural Cycles?</p> <ul style="list-style-type: none"> • Preprečite nosečnost • Načrtujte nosečnost • Sledite svoji nosečnosti
<p>Set your date of birth</p> <p>You must be 18 years of age or older to use Natural Cycles</p>	<p>Določite svoj datum rojstva</p> <p>Če želite uporabljati Natural Cycles, morate biti stari 18 let ali več</p>
<p>Which measurements would you like to use in the app?</p> <p>Height and weight</p> <ul style="list-style-type: none"> • Metric (kg / cm) • Imperial (lb / foot) 	<p>Katere meritve bi radi uporabili v aplikaciji?</p> <p>Višina in teža</p> <ul style="list-style-type: none"> • Metrična (kg / cm) • Imperial (lb / stopalo)
<p>Temperature</p> <ul style="list-style-type: none"> • Celsius • Fahrenheit 	<p>Temperatura</p> <ul style="list-style-type: none"> • Celzija • Fahrenheit
<p>Have you been diagnosed with any of the following?</p> <p>Certain medical conditions can affect your cycle so knowing about them helps us adapt and learn more about you.</p> <ul style="list-style-type: none"> • Polycystic Ovary Syndrome (PCOS) • Endometriosis • A Thyroid-Related Condition 	<p>Ali so vam odkrili kaj od naslednjega?</p> <p>Nekatera zdravstvena stanja lahko vplivajo na vaš cikel, zato nam poznavanje njih pomaga prilagoditi in izvedeti več o vas.</p> <ul style="list-style-type: none"> • Sindrom policističnih jajčnikov (PCOS) • Endometrioza • Stanje, povezano s ščitnico

<p>Have you experienced symptoms of Menopause?</p> <p>Menopause can affect your cycle so knowing about it helps us adapt and learn more about you.</p> <ul style="list-style-type: none"> • Yes • No 	<p>Ste imeli simptome menopavze?</p> <p>Menopavza lahko vpliva na vaš cikel, zato nam poznavanje tega pomaga, da se prilagodimo in izvedemo več o vas.</p> <ul style="list-style-type: none"> • Da • Ne
<p>Have you recently used hormonal contraception?</p> <p>If you are currently, or recently have been, using hormonal contraception such as the pill, an implant, or a vaginal ring, we can optimise the app to best fit your needs.</p> <p><u>Effects on your menstrual cycle</u></p> <p>Hormonal contraception can inhibit your ovulation and cause irregularities in your cycle up to a year after you've stopped using it.</p> <p><u>If you haven't used it recently</u></p> <p>If you stopped using hormonal contraception a year ago and have your period again, then answer 'Not in the last 12 months'.</p> <p>Have you recently used hormonal contraception?</p> <ul style="list-style-type: none"> • Yes, in the past 12 months • Yes, still on it • Not in the last 12 months • No, never 	<p>Ste pred kratkim uporabljali hormonsko kontracepcijo?</p> <p>Če trenutno ali pred kratkim uporabljate hormonsko kontracepcijo, kot so tablete, vsadek ali vaginalni obroč, lahko aplikacijo optimiziramo tako, da najbolje ustreza vašim potrebam.</p> <p><u>Učinki na vaš menstrualni cikel</u></p> <p>Hormonska kontracepcija lahko zavira ovulacijo in povzroči nepravilnosti v vašem ciklu do enega leta po prenehanju uporabe.</p> <p><u>Če ga pred kratkim niste uporabljali</u></p> <p>Če ste pred enim letom prenehali uporabljati hormonsko kontracepcijo in ste spet imeli menstruacijo, odgovorite 'Ne v zadnjih 12 mesecih'.</p> <p>Ste pred kratkim uporabljali hormonsko kontracepcijo?</p> <ul style="list-style-type: none"> • Da, v zadnjih 12 mesecih • Da, še vedno na njem • Ne v zadnjih 12 mesecih • Ne, nikoli

<p>Using Natural Cycles while still on hormonal birth control</p> <p>When you use hormonal birth control (such as the Pill, an implant, or a vaginal ring), you don't ovulate. This means that Natural Cycles won't be able to track your menstrual cycle.</p> <p>While you are using hormonal birth control, we recommend you explore the demo version of the app.</p> <ul style="list-style-type: none"> ● Use in Demo Mode 	<p>Uporaba Natural Cycles, medtem ko ste še vedno na hormonski kontracepciji</p> <p>Ko uporabljate hormonsko kontracepcijo (na primer tableto, vsadek ali vaginalni obroč), ne ovulirate. To pomeni, da Natural Cycles ne bo mogel slediti vašemu menstrualnemu ciklu.</p> <p>Medtem ko uporabljate hormonsko kontracepcijo, vam priporočamo, da raziščete demo različico aplikacije.</p> <ul style="list-style-type: none"> ● Uporabite v demo načinu
<p>Approximately how long does your cycle usually last?</p> <p>A cycle is the time span between one period and the next.</p>	<p>Koliko časa običajno traja vaš cikel?</p> <p>Cikel je časovni interval med enim obdobjem in naslednjim.</p>
<p>How much does the length of your cycle vary?</p> <p>Understanding the regularity of your cycles helps the algorithm get to know you better.</p> <ul style="list-style-type: none"> ● 0-4 Days ● 5-9 Days ● 10+ Days ● I don't know 	<p>Koliko se spreminja dolžina vašega cikla?</p> <p>Razumevanje pravilnosti vaših ciklov pomaga algoritmu, da vas bolje spozna.</p> <ul style="list-style-type: none"> ● 0-4 dni ● 5-9 dni ● Več kot 10 dni ● Ne vem
<p>For how long did you use hormonal contraception?</p> <ul style="list-style-type: none"> ● 0 - 1 Years ● 1 - 5 Years ● 5+ Years 	<p>Kako dolgo ste uporabljali hormonsko kontracepcijo?</p> <ul style="list-style-type: none"> ● 0 - 1 let ● 1 - 5 let ● 5+ let

<p>For how long did you use hormonal contraception?</p> <p>If you have recently used hormonal contraception such as the pill, an implant, or a vaginal ring, we can optimise the app to best fit your needs.</p> <p><u>Effects on your menstrual cycle</u></p> <p>Hormonal contraception can inhibit your ovulation and cause irregularities in your cycle up to a year after you've stopped using it.</p>	<p>Kako dolgo ste uporabljali hormonsko kontracepcijo?</p> <p>Če ste pred kratkim uporabljali hormonsko kontracepcijo, kot so tablete, vsadki ali vaginalni obroč, lahko aplikacijo optimiziramo tako, da najbolje ustreza vašim potrebam.</p> <p><u>Učinki na vaš menstrualni cikel</u></p> <p>Hormonska kontracepcija lahko zavira ovulacijo in povzroči nepravilnosti v vašem ciklu do enega leta po prenehanju uporabe.</p>
<p>Have you had your period since you quit hormonal contraception?</p> <ul style="list-style-type: none"> • Yes • No <p>Have you had your period since you quit hormonal contraception?</p> <p>When you stop using hormonal contraception, you will first experience a so-called "withdrawal bleeding", which is the effect of the hormones leaving your body. It is lighter than your true period. The following bleeding you will get (a few weeks later) will be your natural period.</p> <p>If you have experienced withdrawal bleeding but haven't had your natural period back, answer 'no' to this question.</p> <p>If you have experienced withdrawal bleeding and have had your natural period back, answer 'yes'.</p>	<p>Ali ste imeli menstruacijo, odkar ste prenehali s hormonsko kontracepcijo?</p> <ul style="list-style-type: none"> • Da • Ne <p>Ali ste imeli menstruacijo, odkar ste prenehali s hormonsko kontracepcijo?</p> <p>Ko prenehate uporabljati hormonsko kontracepcijo, boste najprej doživeli tako imenovano "odtegnitveno krvavitev", ki je posledica izločanja hormonov iz telesa. Je lažja od vaše prave menstruacije. Naslednja krvavitev, ki jo boste dobili (nekaj tednov kasneje), bo vaša naravna menstruacija.</p> <p>Če ste imeli odtegnitveno krvavitev, vendar niste imeli naravne menstruacije, odgovorite z "ne" na to vprašanje.</p> <p>Če ste imeli odtegnitveno krvavitev in ste imeli naravno menstruacijo, odgovorite z »da«.</p>
<p>When did you quit hormonal contraception?</p> <ul style="list-style-type: none"> • I don't know 	<p>Kdaj ste prenehali s hormonsko kontracepcijo?</p> <ul style="list-style-type: none"> • Ne vem

<p>When did your last period start?</p> <ul style="list-style-type: none"> • Skip this 	<p>Kdaj se je začela vaša zadnja menstruacija?</p> <ul style="list-style-type: none"> ● Preskoči to
<p>How many cycles have you had since you quit hormonal contraception?</p> <p>A cycle is the time span between one period and the next.</p>	<p>Koliko ciklov ste imeli, odkar ste prenehali s hormonsko kontracepcijo?</p> <p>Cikel je časovni interval med enim obdobjem in naslednjim.</p>
<p>Using Natural Cycles after hormonal contraception</p> <p>Our data show that women transitioning to Natural Cycles from hormonal contraception have a higher risk of becoming pregnant due to generally not yet being accustomed to using other forms of protection.</p> <p>On red days, you must either abstain or use protection, such as condoms (or another form of barrier protection), to prevent pregnancy. If you have not been using a non-hormonal based method of birth control before, make sure to have a method on hand to use during red days, such as condoms.</p> <p>When you discontinue hormonal birth control, you may first experience a withdrawal bleed, which is much lighter than your true period. You will normally get your true period a few weeks later. Withdrawal bleeding should not be entered as “period” into the app. If you are unsure if you are experiencing withdrawal bleeding or a period, please consult your doctor.</p> <p>It can take several cycles after discontinuing hormonal birth control before becoming more regular again. You should expect more red days during these cycles and therefore expect to use protection, such as condoms (or another form of barrier protection), or abstain more frequently.</p>	<p>Uporaba Natural Cycles po hormonski kontracepciji</p> <p>Naši podatki kažejo, da imajo ženske, ki prehajajo na Natural Cycles iz hormonske kontracepcije, večje tveganje zanositve, ker na splošno še niso navajene uporabljati drugih oblik zaščite.</p> <p>V rdečih dneh se morate vzdržati ali uporabljati zaščito, na primer kondome (ali drugo obliko pregradne zaščite), da preprečite nosečnost. Če doslej niste uporabljali nehormonske metode kontracepcije, imejte pri roki metodo za uporabo v rdečih dneh, na primer kondome.</p> <p>Ko prekinete hormonsko kontracepcijo, lahko najprej doživite odtegnitveno krvavitev, ki je veliko lažja od vaše prave menstruacije. Pravo menstruacijo običajno dobite nekaj tednov kasneje. Odtegnitvene krvavitve ne smete vnesti kot »obdobje« v aplikacijo. Če niste prepričani, ali imate odtegnitveno krvavitev ali menstruacijo, se posvetujte z zdravnikom.</p> <p>Po ukinitvi hormonske kontracepcije lahko traja več ciklov, preden postane spet bolj redna. V teh ciklih bi morali pričakovati več rdečih dni in zato pričakovati, da boste uporabljali zaščito, na primer kondome (ali drugo obliko zaščite pred ovirami), ali se bolj vzdržali.</p>

<ul style="list-style-type: none"> • I understand 	<ul style="list-style-type: none"> • Razumem
<p>Have you been pregnant at any point in the past 12 months?</p> <ul style="list-style-type: none"> • Yes • No <p>Have you been pregnant at any point in the past 12 months? If you have recently been pregnant, we can optimize the app to best fit your needs. Effects on your menstrual cycle After pregnancy, your cycle may be irregular and you might not ovulate.</p>	<p>Ali ste bili v zadnjih 12 mesecih kdaj noseči?</p> <ul style="list-style-type: none"> • Da • Ne <p>Ali ste bili v zadnjih 12 mesecih kdaj noseči? Če ste bili nedavno noseči, lahko aplikacijo optimiziramo tako, da najbolje ustreza vašim potrebam. Učinki na vaš menstrualni cikel Po nosečnosti je lahko vaš cikel nepravilen in morda ne boste ovulirali.</p>
<p>Have you had your period since your pregnancy ended? (not the initial bleeding)</p> <ul style="list-style-type: none"> • Yes • No 	<p>Ali ste imeli menstruacijo po koncu nosečnosti? (ne začetna krvavitev)</p> <ul style="list-style-type: none"> • Da • Ne
<p>How many cycles have you had since your pregnancy?</p>	<p>Koliko ciklov ste imeli od nosečnosti?</p>
<p>When did your pregnancy end?</p>	<p>Kdaj se je vaša nosečnost končala?</p>
<p>Have you had your period since your pregnancy ended? (not the initial bleeding) If you start to menstruate again, you have had a complete menstrual cycle. If you have not had your period since your pregnancy ended, then you haven't yet started your menstrual cycle.</p>	<p>Ali ste imeli menstruacijo po koncu nosečnosti? (ne začetna krvavitev) Če imate spet menstruacijo, ste imeli popoln menstrualni cikel. Če niste imeli menstruacije po koncu nosečnosti, potem še niste začeli menstrualnega cikla.</p>
<p>The initial bleeding The initial bleeding after your pregnancy ended is not a part of your menstrual cycle.</p>	<p>Začetna krvavitev Začetna krvavitev po koncu nosečnosti ni del vašega menstrualnega cikla.</p>

<p>Using Natural Cycles while breastfeeding</p> <p>For the first 4–6 months after giving birth, many women who are exclusively breastfeeding may not ovulate. Natural Cycles will detect your first ovulation 2 weeks before your first menstruation, but until then you will only see red days in the app. Even though you are not ovulating, it is still important to use contraception or abstain from intercourse on red days.</p> <ul style="list-style-type: none"> ● I understand ● Learn more 	<p>Uporaba Natural Cycles med dojenjem</p> <p>Prve 4-6 mesecev po porodu mnoge ženske, ki dojijo izključno, morda ne bodo ovulirale. Natural Cycles bo zaznala vašo prvo ovulacijo 2 tedna pred prvo menstruacijo, do takrat pa boste v aplikaciji videli le rdeče dni. Čeprav nimate ovulacije, je še vedno pomembno, da uporabite kontracepcijo ali se vzdržite spolnega odnosa v rdečih dneh.</p> <ul style="list-style-type: none"> ● Razumem ● Več o tem
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<p>In-app information for safety and performance</p> <p>The following words and sentences in the app are related to the safety and performance of the device and are therefore provided in a translated version here in the User manual.</p>	<p>Podatki o varnosti in zmogljivosti</p> <p>v aplikaciji Naslednje besede in stavki v aplikaciji so povezani z varnostjo in zmogljivostjo naprave in so zato v prevedeni različici navedeni v uporabniškem priročniku.</p>
<p>Angleščina</p>	<p>Slovenščina</p>
<p>NC° Birth Control</p> <ul style="list-style-type: none"> ● Use protection ● Not fertile ● Emergency contraception and tests ● Emergency contraception ● Pill ● IUD (Intrauterine Device) - Intrauterine Device 	<p>NC° Birth Control</p> <ul style="list-style-type: none"> ● Uporabite zaščito ● Ni plodna ● Nujna kontracepcija in testi ● Nujna kontracepcija ● Tabletko ● IUD (Intrauterine Device) - Intrauterina naprava
<p>NC° Plan Pregnancy</p> <ul style="list-style-type: none"> ● Not fertile ● Low fertility ● Medium fertility 	<p>NC° Plan Pregnancy</p> <ul style="list-style-type: none"> ● Ni plodna ● Nizka rodnost ● Srednja rodnost

<ul style="list-style-type: none"> ● High fertility ● Very high fertility ● Peak fertility ● Fertility unlikely ● More data needed 	<ul style="list-style-type: none"> ● Visoka rodnost ● Zelo visoka rodnost ● Najvišja rodnost ● Plodnost malo verjetna ● Potrebni je več podatkov
<p>General</p> <ul style="list-style-type: none"> ● Confirmed ovulation ● Ovulation ● Today ● Cycle day ● Monday ● Tuesday ● Wednesday ● Thursday ● Friday ● Saturday ● Sunday ● Predictions - do not take as result ● Exclude temperature ● Sick ● Slept differently ● Hungover ● Bleeding ● Period ● Spotting ● Sex ● Protected ● Unprotected ● None ● LH test ● Positive ● Negative ● Compare ● Pregnancy test ● No longer pregnant ● More ● Less ● Save ● Done ● Clear ● Skip ● Regulatory ● Version 	<p>Splošno</p> <ul style="list-style-type: none"> ● Potrjena ovulacija ● ovulacija ● Danes ● dan cikla ● ponedeljek ● torek ● sreda ● četrtek ● petek ● sobota ● nedelja ● Napovedi - ne upoštevajte ● Izključi temperaturo ● bolan ● Spal drugače ● Mačka ● krvavitev ● Obdobje ● Odkrivanje ● Seks ● Zaščiteno ● Nezaščiteno ● Brez ● LH test ● Pozitivno ● Negativno ● Primerjaj ● test nosečnosti ● Niste več noseči ● Več ● Manj ● Shrani ● Končano ● Počisti ● Preskoči ● Regulativno ● Različica

APPENDIX: This table provides information about the effectiveness of different contraceptive methods ranging from least effective to most effective under typical use.

Reference: Contraceptive Technology (Table 26 - 1). 21st Edition, 2018.

Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year. United States.

Method	% of women experiencing an unintended pregnancy within the First Year of Use		% of women continuing use at one year ³
	Typical use ¹	Perfect use ²	
No method ⁴	85	85	
Spermicides ⁵	21	16	42
Female Condom ⁶	21	5	41
Withdrawal	20	4	46
Diaphragm ⁷	17	16	57
Sponge	17	12	36
Parous Women	27	20	
Nulliparous Women	14	9	
Fertility awareness-based methods ⁸	15		47
Ovulation method ⁸	23	3	
TwoDay method ⁸	14	4	
Standard Days method ⁸	12	5	
Natural Cycles ⁸	8	1	
Symptothermal method ⁸	2	0.4	
Male condom ⁶	13	2	43
Combined and progestin-only pill	7	0.3	67
Evra patch	7	0.3	67
NuvaRing	7	0.3	67
Depo-Provera	4	0.2	56
Intrauterine contraceptives			
ParaGard (copper T)	0.8	0.6	78
Skyla (13.5 mg LNG)	0.4	0.3	
Kyleena (19.5mg LNG)	0.2	0.2	
Liletta (52mg LNG)	0.1	0.1	
Mirena (52mg LNG)	0.1	0.1	80

Nexplanon	0.1	0.1	89
Tubal occlusion	0.5	0.5	100
Vasectomy	0.15	0.1	100

Emergency Contraceptives: Use of emergency contraceptive pills or placement of a copper intrauterine contraceptive after unprotected intercourse substantially reduces the risk of pregnancy.

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.⁹

1 Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any reason other than pregnancy. Estimates of the probability of pregnancy during the first year of typical use for fertility awareness-based methods, withdrawal, the male condom, the pill, and Depo-Provera are taken from the 2006–2010 National Survey of Family Growth (NSFG) corrected for under-reporting of abortion. See the text for the derivation of estimates for the other methods.

2 Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method

3 Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.

4 This estimate represents the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether. See text.

5 150 mg gel, 100 mg gel, 100 mg suppository, 100 mg film.

6 Without spermicides.

7 With spermicidal cream or jelly

8 About 80% of segments of FABM use in the 2006-2010 NSFG were reported as calendar rhythm. Specific FABM methods are too uncommonly used in the U.S. to permit calculation of typical use failure rates for each using NSFG data; rates provided for individual methods are derived from clinical studies. The Ovulation and TwoDay methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19. Natural Cycles is a fertility app that requires user input of basal body temperature (BBT) recordings and dates of menstruation and optional LH urinary test results. The Symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

9 However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.